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Vol. 17

Consolidated Guidance About Materials Licenses

Program-Specific Guidance About Special Nuclear Material of Less Than Critical Mass Licenses

Final Report

U.S. Nuclear Regulatory Commission

Office of Nuclear Material Safety and Safeguards

C.F. Frazier, J. Cruz, S.W. Shaffer

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ABSTRACT

As part of its redesign of the materials licensing process, NRC is consolidating and updating numerous guidance documents into a single comprehensive repository, as described in NUREG-1539, "Methodology and Findings of the NRC's Materials Licensing Process Redesign," dated April 1996, and draft NUREG-1541, "Process and Design for Consolidating and Updating Materials Licensing Guidance," dated April 1996. NUREG-1556, Vol. 17, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance About Special Nuclear Material of Less Than Critical Mass Licenses," dated November 2000, is the seventeenth program-specific guidance developed for the new process and is intended for use by applicants, licensees, and NRC staff, and will also be available to Agreement States. This document combines and updates the guidance found in Regulatory Guide 10.3, "Guide for the Preparation of Applications for Special Nuclear Material Licenses of Less Than Critical Mass Quantities." The report takes a risk-informed, performance-based approach to licensing quantities of special nuclear material of less than critical mass, and reduces the information (amount and level of detail) needed to support an application to use this material.

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FOREWORD

The United States Nuclear Regulatory Commission (NRC) is using Business Process Redesign (BPR) techniques to redesign its materials licensing process. This effort is described in NUREG-1539, "Methodology and Findings of the NRC's Materials Licensing Process Redesign," dated April 1996. A critical element of the new process is consolidating and updating numerous guidance documents into a NUREG-series of reports. Below is a listing of volumes currently included in the NUREG-1556 series:

Vol. No.	Volume Title	Status
1	Program-Specific Guidance About Portable Gauge Licenses	Final Report
2	Program-Specific Guidance About Radiography Licenses	Final Report
3	Applications for Sealed Source and Device Evaluation and Registration	Final Report
4	Program-Specific Guidance About Fixed Gauge Licenses	Final Report
5	Program-Specific Guidance about Self-Shielded Irradiators	Final Report
6	Program-Specific Guidance about 10 CFR Part 36 Irradiators	Final Report
7	Program-Specific Guidance about Academic, Research and Development, and Other Licenses of Limited Scope	Final Report
8	Program-Specific Guidance about Exempt Distribution Licenses	Final Report
9	Program-Specific Guidance about Medical Use Licenses	Draft
10	Program-Specific Guidance about Master Material Licenses	Draft
11	Program-Specific Guidance about Licenses of Broad Scope	Final Report
12	Program-Specific Guidance about Possession Licenses for Manufacturing and Distribution	Draft
13	Program-Specific Guidance about Commercial Radiopharmacy Licenses	Final Report
14	Program-Specific Guidance about Well Logging, Tracer, and Field Flood Study Licenses	Final Report
15	Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses	Draft
16	Program-Specific Guidance About Licenses Authorizing Distribution To General Licensees	Draft

Vol. No.	Volume Title	Status
17	Program-Specific Guidance About Special Nuclear Material of Less Than Critical Mass Licenses	Final Report
18	Program-Specific Guidance About Service Provider Licenses	Draft
19	Guidance For Agreement State Licensees Proposing to Work in NRC Jurisdiction (Non-Agreement States, Areas of Exclusive Federal Jurisdiction, or Offshore Waters) and Guidance For NRC Licensees Proposing to Work in Agreement State Jurisdiction (Reciprocity)	Draft
20	Guidance About Administrative Licensing Procedures	Draft

The current document, NUREG-1556, Vol. 17, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance About Special Nuclear Material of Less Than Critical Mass Licenses," dated November 2000, is the seventeenth program-specific guidance developed for the new process. It is intended for use by applicants, licensees, NRC license reviewers, and other NRC personnel. It combines and updates the guidance for applicants and licensees previously found in Regulatory Guide 10.3, "Guide for the Preparation of Applications for Special Nuclear Material Licenses of Less Than Critical Mass Quantities." In addition, this report also contains pertinent information found in additional documents consulted during preparation of this document, as listed in Appendix A.

The risk-informed, performance-based approach to licensing quantities of Special Nuclear Material (SNM) of less than critical mass taken by the report, reduces the amount of information needed from an applicant seeking to possess and use quantities of SNM.

A team composed of NRC staff from Headquarters and Regional Offices developed this document, drawing on their collective experience in radiation safety in general, and as specifically applied to SNM. A representative of NRC's Office of the General Counsel provided a legal perspective.

NUREG-1556, Vol. 17, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance About Special Nuclear Material of Less Than Critical Mass Licenses," dated November 2000, represents a step in the transition from the current paper-based process to the new electronic process. This document is available on the Internet at the following address: <http://www.nrc.gov/NRC/NUREGS/SR1556/V17/index.html>.

NUREG-1556, Vol. 17, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance About Special Nuclear Material of Less Than Critical Mass Licenses," dated November 2000, is not a substitute for NRC regulations, and compliance is not required. The approaches and methods described in this report are provided for information only.

Donald A. Cool, Director
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Office of Nuclear Material Safety and Safeguards

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ABBREVIATIONS

ALARA	as low as is reasonably achievable
ANSI	American National Standards Institute
bkg	background
BPR	business process redesign
Bq	Becquerel
CFR	Code of Federal Regulations
cpm	counts per minute
DOE	United States Department of Energy
DOT	United States Department of Transportation
G-M	Geiger-Mueller
GPO	Government Printing Office
Gy	gray
IN	Information Notice
L/C	License Condition
mGy	milligray
mR	milliroentgen
mrem	millirem
mSv	millisievert
NCRP	National Council on Radiation Protection and Measurements
NIST	National Institute of Standards and Technology
NMSS	Office of Nuclear Material Safety and Safeguards
NRC	Nuclear Regulatory Commission
NVLAP	National Voluntary Laboratory Accreditation Program
OCFO	Office of the Chief Financial Officer
OCR	optical character reader
OMB	Office of Management and Budget
QA	quality assurance
R	Roentgen
RG	Regulatory Guide
RIS	Reporting Identification Symbol
RQ	reportable quantities
RSO	radiation safety officer
SDE	shallow dose equivalent
SI	International System of Units (abbreviated SI from the French Le Systeme Internationale d'Unites)
SNM	Special Nuclear Material
SSD	sealed source and device
std	standard
Sv	Sievert
TAR	technical assistance request
TEDE	total effective dose equivalent
TI	transportation index
TLD	thermoluminescent dosimeters
UN	United Nations
ZnS	zinc sulfide

1 PURPOSE OF REPORT

This report provides guidance to an applicant in preparing a license application for a specific license for receipt, possession, use, and transfer of special nuclear material in quantities less than "critical mass" as well as NRC criteria for evaluating a license application for special nuclear material. Within this document "special nuclear material," "licensed material," or "radioactive material," are used interchangeably.

Special Nuclear Material as defined in 10 CFR Part 70 means plutonium (Pu), uranium (U)-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material that the Commission determines to be special nuclear material or any material artificially enriched by any of the foregoing. Typical uses include:

- Experiments using sub-critical assemblies;
- Foil activation experiments using Pu-238/Beryllium (Be) sources;
- Instrument calibration;
- Student instruction in radiation detection and measurement;
- Nuclear pacemakers;
- U-235 target foils experiments.

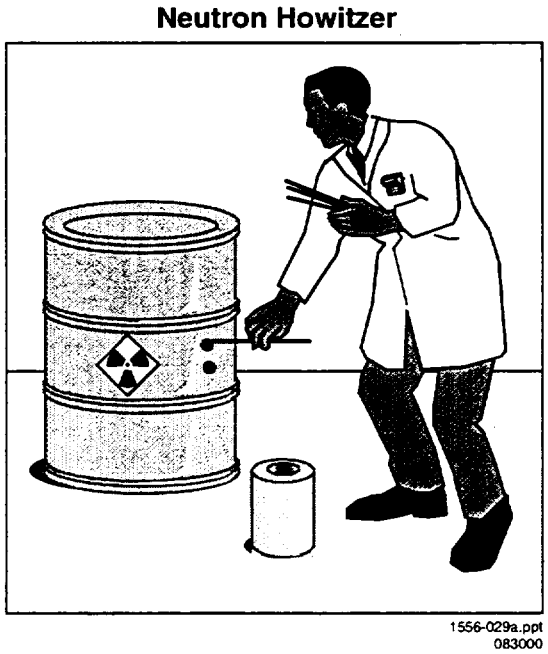

Figure 1.1 A Typical Research Use of Special Nuclear Material.

This guide is intended for applicants requesting authorization to possess and use up to 2,000 grams of plutonium, total, in the form of sealed Pu-Be neutron sources, and any special nuclear material in quantities and forms not sufficient to form a critical mass, as stated in 10 CFR 150.11. The latter quantities are considered to be up to 350 grams of contained U-235,

200 grams of U-233, 200 grams of plutonium (in any form other than Pu-Be neutron sources), or any combination of them in accordance with the following formula:

$$\frac{\text{grams U-235}}{350} + \frac{\text{grams U-233}}{200} + \frac{\text{grams Pu}}{200} \leq 1$$

This guide describes the type of information needed to evaluate an application for a specific license for receipt, possession, use, and transfer of special nuclear material. For each kind of special nuclear material, the applicant should determine the ratio between the requested quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of such ratios for all kinds of special nuclear material in combination, should not exceed unity. For example, the following in combination would not exceed the limitation of the formula:

$$\frac{175\ \text{(grams contained U-235)}}{350} + \frac{50\ \text{(grams U-233)}}{200} + \frac{50\ \text{(grams Pu)}}{200} = 1$$

$$.5 + .25 + .25 = 1$$

This guide is not intended to address the following issues:

- Possession of quantities of special nuclear material in excess of critical mass;
- Licenses authorizing manufacturing and distribution of SNM.

This report identifies the information needed to complete NRC Form 313 (Appendix B), "Application for Material License," or letter of application for the use of unsealed and sealed special nuclear material. The information collection requirements in 10 CFR Part 70 and NRC Form 313 have been approved under the Office of Management and Budget (OMB) Clearance Nos. 3150-0009 and 3150-0120, respectively.

The format within this document for each item of technical information is as follows:

- Regulations – references the regulations applicable to the item;
- Criteria – outlines the criteria used to judge the adequacy of the applicant's response;
- Discussion – provides additional information on the topic sufficient to meet the needs of most readers;
- Response from Applicant – provides suggested response(s), offers the option of an alternative reply, or indicates that no response is needed on that topic during the licensing process.

Notes and references are self-explanatory and may not be found for each item on NRC Form 313.

NRC Form 313 does not have sufficient space for applicants to provide full responses to Items 5 through 11; as indicated on the form, the answers to those items are to be provided on separate sheets of paper and submitted with the completed NRC Form 313. For the convenience of

applicants and for streamlined handling of special nuclear material applications in the new materials licensing process, use Appendix C to provide supporting information, attach it to NRC Form 313, and submit them to NRC.

Appendix C is a checklist that NRC staff uses to review applications and applicants can use to check for completeness. Appendices D through O contain additional information on various radiation safety topics, including model procedures. Appendix N is a sample SNM license, containing the conditions most often found on these licenses, although not all licenses will have all conditions (a sample Nuclear Pacemaker license can be found in Appendix C of draft NUREG-1556, Vol. 9, "Consolidated Guidance About Materials Licenses; Program-Specific Guidance about Medical Use Licenses," dated August 1998). Appendix O includes a table of NRC incident notification and reporting requirements applicable to special nuclear material.

In this document, dose or radiation dose means absorbed dose, dose equivalent, effective dose equivalent (EDE), committed dose equivalent (CDE), committed effective dose equivalent (CEDE), or total effective dose equivalent (TEDE). These terms are defined in 10 CFR Part 20. Rem, and its SI equivalent sievert (1 rem = 0.01 sievert (Sv)), are used to describe units of radiation exposure or dose. This is done because 10 CFR Part 20 sets dose limits in terms of rem, not rad or roentgen (R). When the radioactive material emits beta and gamma rays, for practical reasons we are assuming that 1 R = 1 rad = 1 rem. For neutron and alpha emitting radioactive material, 1 rad is not equal to 1 rem. Determination of dose equivalent (rem) from absorbed dose (rad) from neutrons and alpha particles requires the use of an appropriate quality factor (Q) value. Q values are used to convert absorbed dose (rad) to dose equivalent (rem). Q values for neutrons and alpha particles are addressed in the Tables 1004(b)(1) and (2) in 10 CFR 20.1004.

2 AGREEMENT STATES

Certain states, called Agreement States (see Figure 2.1), have entered into agreements with NRC that give them the authority to license and inspect byproduct, source, or special nuclear materials used or possessed within their borders. Any applicant other than a Federal agency who wishes to possess or use licensed material in one of these Agreement States needs to contact the responsible officials in that state for guidance on preparing an application. These applications should be filed with state officials, not with NRC.

NRC's materials licensees who wish to conduct operations under reciprocity at temporary job sites in an Agreement State, and who are specifically authorized on the license to conduct such activities, should contact that state's Radiation Control Program Office for information about state regulations and questions of jurisdiction on Federal lands or facilities within that Agreement State's boundaries. To ensure compliance with Agreement State reciprocity requirements, licensees should request authorization well in advance of scheduled use.

In the special situation of work at Federally-controlled sites in Agreement States, it is necessary to know the jurisdictional status of the land in order to determine whether NRC or the Agreement State has regulatory authority. NRC has regulatory authority over land determined to be "exclusive Federal jurisdiction," while the Agreement State has jurisdiction over non-exclusive Federal jurisdiction land. Licensees are responsible for finding out, in advance, the jurisdictional status of the specific areas where they plan to conduct licensed operations. NRC recommends that licensees ask their local contact for the Federal agency controlling the site (e.g., contract officer, base environmental health officer, district office staff) to help determine the jurisdictional status of the land and to provide the information in writing, so that licensees can comply with NRC or Agreement State regulatory requirements, as appropriate. Additional guidance on determining jurisdictional status is found in All Agreement States Letter, SP-96-022, dated February 16, 1996, which is available from NRC upon request.

Table 2.1 provides a quick way to check on which agency has regulatory authority.

Table 2.1 Who Regulates the Activity?

Applicant and Proposed Location of Work	Regulatory Agency
Federal agency regardless of location (except that Department of Energy [DOE] and, under most circumstances, its prime contractors are exempt from licensing [10 CFR 70.11])	NRC
Non-Federal entity in non-Agreement State, U.S. territory, or possession	NRC
Non-Federal entity in Agreement State at non-Federally controlled site	Agreement State
Non-Federal entity in Agreement State at Federally-controlled site not subject to exclusive Federal jurisdiction	Agreement State
Non-Federal entity in Agreement State at Federally-controlled site subject to exclusive Federal jurisdiction	NRC

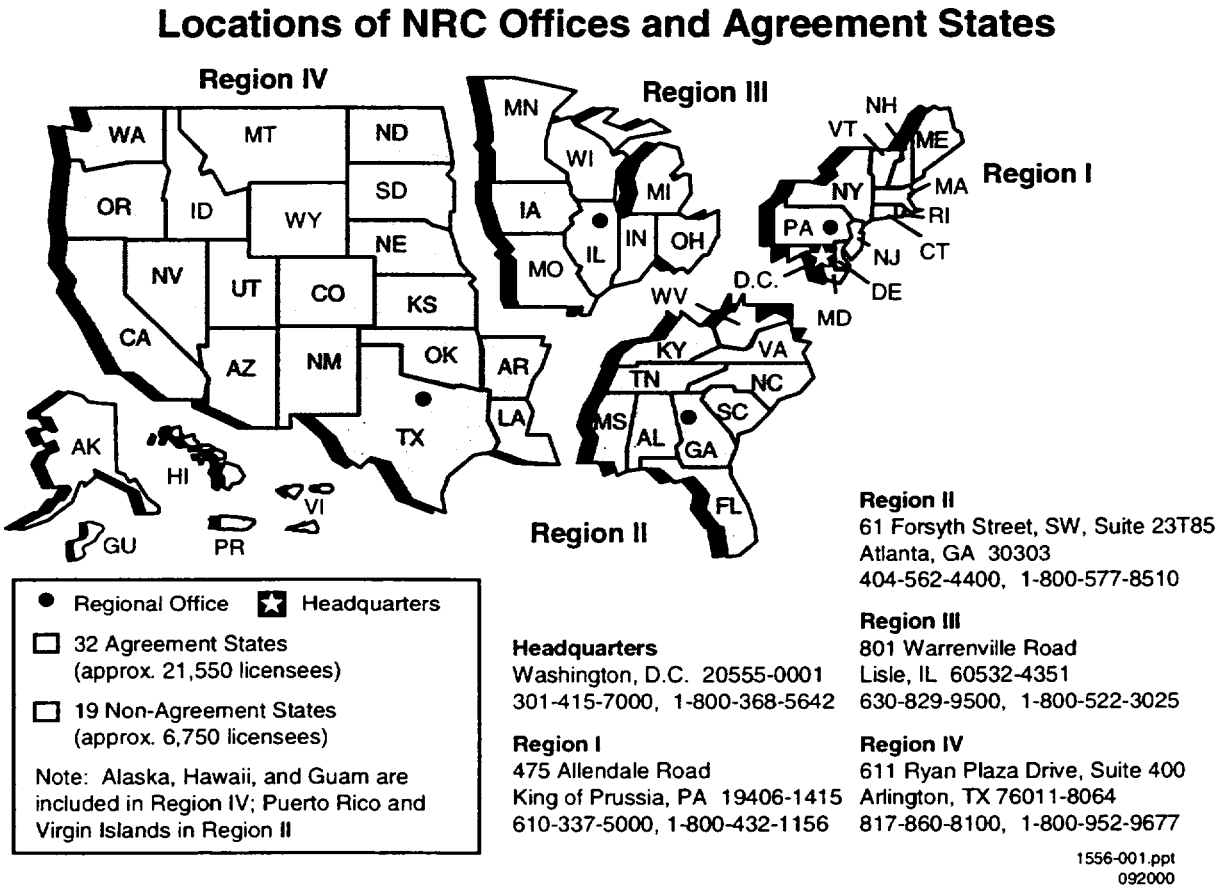

Figure 2.1 U.S. Map. *Location of NRC Offices and Agreement States.*

References: A current list of Agreement States (including names, addresses, and telephone numbers of responsible officials) may be obtained upon request from NRC's Regional Offices. You can also visit the NRC Office of State and Tribal Programs' (STP's) Home Page <http://www.hsrd.ornl.gov/nrc> and choose "Directories," then "State Program Directors."

All Agreement States Letter, SP-96-022, dated February 16, 1996, is available by calling STP. Call NRC's toll free number (800) 368-5642, and then ask for extension 415-3340, or visit the NRC Office of State and Tribal Programs' (STP's) Home Page <http://www.hsrd.ornl.gov/nrc> and choose "NRC-State Communications," then choose "Other"; scroll down to find "1996" then "SP-96-022."

3 MANAGEMENT RESPONSIBILITY

NRC recognizes that effective radiation safety program management is vital to achieving safe and compliant operations. NRC believes that consistent compliance with its regulations provides reasonable assurance that licensed activities will be conducted safely. NRC also believes that effective management will result in increased safety and compliance.

"Management" refers to the processes for conducting and controlling the radiation safety program and to the individuals who are responsible for those processes and who have *authority to provide necessary resources* to achieve regulatory compliance.

To ensure adequate management involvement, a management representative must sign the submitted application acknowledging management's commitments and responsibility for the following:

- Radiation safety, security and control of radioactive materials, and compliance with regulations;
- Completeness and accuracy of the radiation safety records and all information provided to NRC (10 CFR 70.9);
- Knowledge about the contents of the license and application;
- Compliance with current NRC and Department of Transportation (DOT) regulations and the licensee's operating and emergency procedures;
- Commitment to provide adequate resources (including space, equipment, personnel, time, and, if needed, contractors) to the radiation protection program to ensure that public and workers are protected from radiation hazards and meticulous compliance with regulations is maintained;
- Selection and assignment of a qualified individual to serve as the Radiation Safety Officer (RSO) for licensed activities;
- Prohibition against discrimination of employees engaged in protected activities (10 CFR 70.7);
- Commitment to provide information to employees regarding the employee protection and deliberate misconduct provisions in 10 CFR 70.7 and 10 CFR 70.10, respectively;
- Obtaining NRC's prior written consent before transferring control of the license; and
- Notifying appropriate NRC Regional Administrator in writing, immediately following filing of petition for voluntary or involuntary bankruptcy.

For information on NRC inspection, investigation, enforcement, and other compliance programs, see the current version of "General Statement of Policy and Procedures for NRC Enforcement Actions," NUREG-1600, and Manual Chapter (MC) 87110, Appendix A, "Industrial/Academic/Research Inspection Field Notes." NUREG-1600 is available electronically at <http://www.nrc.gov/OE>. For hard copies of NUREG-1600 and MC 87110, see the Notice of Availability (on the inside front cover of this report).

4 APPLICABLE REGULATIONS

It is the applicant's or licensee's responsibility to obtain up-to-date copies of applicable regulations and to abide by each applicable regulation.

The following Parts of 10 CFR Chapter I contain regulations applicable to Special Nuclear Material of Less than Critical Mass:

- 10 CFR Part 2, "Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders"
- 10 CFR Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations"
- 10 CFR Part 20, "Standards for Protection Against Radiation"
- 10 CFR Part 21, "Reporting of Defects and Noncompliance"
- 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material"
- 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material"
- 10 CFR Part 71, "Packaging and Transportation of Radioactive Material"

Part 71 requires that licensees or applicants who transport licensed material or who may offer such material to a carrier for transport must comply with the applicable requirements of the DOT that are found in 49 CFR Parts 170 through 189. Copies of DOT regulations can be ordered from the Government Printing Office (GPO), whose address and telephone number are listed below.

- 10 CFR Part 74, "Material Control and Accounting of Special Nuclear Material"
- 10 CFR Part 150 "Exemptions and Continued Regulatory Authority in Agreement States and in Offshore Waters Under Section 274"
- 10 CFR Part 170, "Fees for Facilities, Materials, Import and Export Licenses and Other Regulatory Services Under the Atomic Energy Act of 1954, as Amended"
- 10 CFR Part 171, "Annual Fees for Reactor Operating Licenses, and Fuel Cycle Licenses and Materials Licenses, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals and Government Agencies Licensed by NRC."

To request copies of the above documents, call GPO's order desk in Washington, DC at (202) 512-1800. Order the two-volume bound version of Title 10, Code of Federal Regulations, Parts 0-50 and 51-199 from the GPO, Superintendent of Documents, Post Office Box 371954, Pittsburgh, Pennsylvania 15250-7954. You may also contact GPO electronically at <http://www.gpo.gov>. Request single copies of the above documents from NRC's Regional Offices (see Figure 2.1 for addresses and telephone numbers). Note that NRC publishes amendments to its regulations in the *Federal Register*. In addition, note that documents can be accessed on NRC's web page at <http://www.nrc.gov.\>.

5 HOW TO FILE

5.1 PAPER APPLICATION

Applicants for a materials license should do the following:

- Be sure to use the most recent guidance in preparing an application;
- Complete NRC Form 313 (Appendix B) Items 1 through 4, 12, and 13 on the form itself;
- Complete NRC Form 313 Items 5 through 11 on supplementary pages or use Appendix C;
- For each separate sheet, other than Appendix C, that is submitted with the application, identify and key it to the item number on the application or the topic to which it refers;
- Submit all documents on 8-1/2 x 11 inch paper;
- Avoid submitting proprietary information unless it is absolutely necessary;
- Submit an original, signed application and one copy;
- Retain one copy of the license application for future reference.

As required by 10 CFR 70.22(d), applications shall be signed by a duly authorized management representative; see Section 8.13, "Certification."

Using the suggested wording of responses and committing to using the model procedures in this report will expedite NRC's review.

All license applications will be available for review by the general public in NRC's Public Document Rooms. If it is necessary to submit proprietary information, follow the procedure in 10 CFR 2.790. Failure to follow this procedure could result in disclosure of the proprietary information to the public or substantial delays in processing the application. Employee personal information, i.e., home address, home telephone number, social security number, date of birth, radiation dose information, should not be submitted unless specifically requested by NRC.

As explained in the "Foreword," NRC's new licensing process will be faster and more efficient, in part, through acceptance and processing of electronic applications at some future date. NRC will continue to accept paper applications. However, these will be scanned and put through an optical character reader (OCR) to convert them to electronic format. To ensure a smooth transition, applicants are requested to follow these suggestions:

- Submit printed or typewritten, not handwritten, text on smooth, crisp paper that will feed easily into the scanner;
- Choose typeface designs that are sans serif, such as Arial, Helvetica, Futura, Univers; the text of this document is in a serif font called Times New Roman;

- Choose 12-point or larger font size;
- Avoid stylized characters such as script, italic, etc.;
- Be sure the print is clear and sharp;
- Be sure there is high contrast between the ink and paper (black ink on white paper is best).

5.2 ELECTRONIC APPLICATION

As the electronic licensing process develops, it is anticipated that NRC may provide mechanisms for filing applications via diskettes or CD-ROM, and through the Internet. Additional filing instructions will be provided as these new mechanisms become available. The existing paper process may also be used.

6 WHERE TO FILE

Applicants wishing to possess or use licensed material in any state or U.S. territory or possession subject to NRC jurisdiction must file an application with the NRC Regional Office for the locale in which the material will be possessed and/or used. Figure 2.1 shows NRC's four Regional Offices and their respective areas for licensing purposes. Figure 2.1 also identifies Agreement States.

In general, applicants wishing to possess or use licensed material in Agreement States must file an application with the Agreement State, not NRC. However, if work will be conducted at Federally controlled sites in Agreement States, applicants must first determine the jurisdictional status of the land in order to determine whether NRC or the Agreement State has regulatory authority. See Section 2, "Agreement States," for additional information.

7 LICENSE FEES

Each application for which a fee is specified must be accompanied by the appropriate fee. Refer to 10 CFR 170.31 to determine the amount of the fee. NRC will not issue the licensing action prior to fee receipt. Consult 10 CFR 170.11 for information on exemptions from these fees. Once technical review has begun, no fees will be refunded; application fees will be charged regardless of the NRC's disposition of an application or the withdrawal of an application.

Most NRC licensees are also subject to annual fees; refer to 10 CFR 171.16. Consult 10 CFR 171.11 for information on exemptions from annual fees and 10 CFR 171.16(c) on reduced annual fees for licensees that qualify as "small entities."

Direct all questions about NRC's fees or completion of Item 12 of NRC Form 313 (Appendix B) to the Office of the Chief Financial Officer (OCFO) at NRC headquarters in Rockville, Maryland, (301) 415-7554. Information about fees may also be obtained by calling NRC's toll- free number (800) 368-5642, extension 415-7554. The e-mail address is fees@nrc.gov.

8 CONTENTS OF AN APPLICATION

The following comments apply to the indicated items on NRC Form 313 (Appendix B).

8.1 ITEM 1: LICENSE ACTION TYPE

THIS IS AN APPLICATION FOR (Check appropriate item):

Type of Action	License No.
❒ A. New License	Not Applicable
❒ B. Amendment	XX-XXXX
❒ C. Renewal	XX-XXXX

Check box A for a new license request.

Check box B for an amendment[1] to an existing license, and provide license number.

Check box C for a renewal[1] of an existing license, and provide license number.

8.2 ITEM 2: APPLICANT'S NAME AND MAILING ADDRESS

List the legal name of the applicant's corporation or other legal entity with direct control over use of the radioactive material; a division or department within a legal entity may not be a licensee. An individual may be designated as the applicant only if the individual is acting in a private capacity and the use of the radioactive material is not connected with employment in a corporation or other legal entity. Provide the mailing address where correspondence should be sent. A Post Office box number is an acceptable mailing address.

Notify NRC of changes in mailing address; these changes do not require a fee.

Note: NRC must be notified before control of the license is transferred or when bankruptcy proceedings have been initiated. See below for more details. NRC Information Notice (IN) 97-30, "Control of Licensed Material during Reorganizations, Employee-Management Disagreements, and Financial Crises," dated June 3, 1997, discusses the potential for the security and control of licensed material to be compromised during periods of organizational instability.

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[1] See Section 9, "Amendments and Renewals to a License," later in this document. Licensees are required to request and obtain an amendment to the license before making changes in their radiation safety program. Examples of changes that require amendments are: change of responsible person or authorized user(s), changes in areas of use, and changes in licensed material, including increases in possession limit of licensed material.

Timely Notification of Change of Control

Regulations: 10 CFR 70.36.

Criteria: The regulations require that "No license issued or granted pursuant to the regulations, nor any right under a license, shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person, unless the Commission shall, after securing full information, find that the transfer is in accordance with the provisions of the Act and shall give its consent in writing." Therefore, licensees must provide full information and obtain NRC's *prior written consent* before transferring control of the license, or, as some licensees call it, "transferring the license."

Discussion: Change of control may be the result of mergers, buyouts, or majority stock transfers. Although it is not NRC's intent to interfere with the business decisions of licensees, it is necessary for licensees to obtain prior NRC written consent. This is to ensure the following:

- Radioactive materials are possessed, used, or controlled only by persons who have valid NRC licenses;
- Materials are properly handled and secured;
- Persons using these materials are competent and committed to implementing appropriate radiological controls;
- A clear chain of custody is established to identify who is responsible for final disposal of the special nuclear material; and
- Public health and safety are not compromised by the use of such materials.

Response from Applicant: Persons who are in the process of applying for an NRC license and who do not already hold one or more other NRC licenses are not subject to NRC regulations with regard to bankruptcy or changes of control. However, applicants must advise NRC of any change of control or bankruptcy that results in changes to the information being reviewed by NRC in the application review process, and that would impact the basis on which NRC would eventually issue the license; Appendix D, excerpted from IN 89-25 (Rev. 1), "Unauthorized Transfer of Ownership or Control of Licensed Activities," dated December 7, 1994, identifies the information to be provided about transferring control.

Notification of Bankruptcy Proceedings

Regulation: 10 CFR 70.32(a)(9).

Criteria: Immediately following filing of voluntary or involuntary petition for bankruptcy for or against a licensee, the licensee must notify the appropriate NRC Regional Administrator, in writing, identifying the bankruptcy court in which the petition was filed and the date of filing.

Response from Applicant: None at time of application for a new license. Generally, licensees should notify NRC within 24 hours of filing a bankruptcy petition.

References: INs are available in the "Reference Library" on NRC's Home Page at <http://www.nrc.gov>. For hard copies, see the Notice of Availability (on the inside front cover of this report). In addition, note that documents can be accessed on NRC's web page at <http://www.nrc.gov.\> Further information can be obtained from draft NUREG-1556, Vol. 15, "Consolidated Guidance About Materials Licenses: Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses."

8.3 ITEM 3: ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

Specify the street address, city, and state or other descriptive address (e.g., on Highway 28, 7 miles east of the intersection of Highway 18 and State Route 160, Anytown, State) for each facility. The descriptive address should be sufficient to allow an NRC inspector to find the facility location. A Post Office Box address is not acceptable, as illustrated in Fig. 8.1.

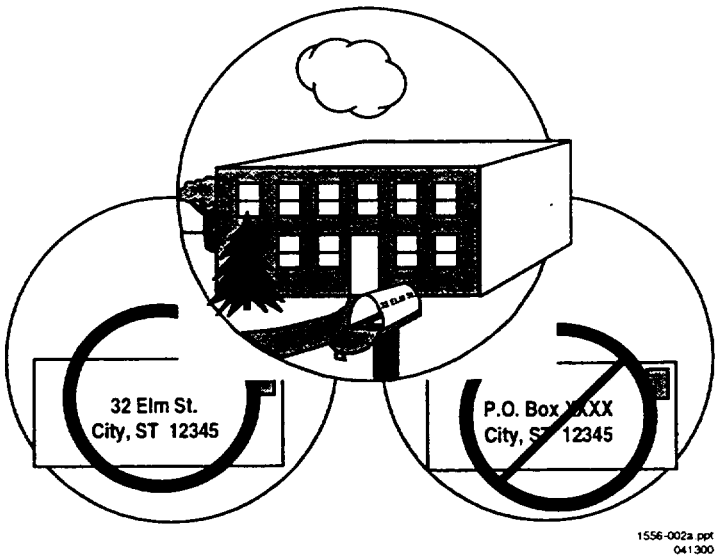

Figure 8.1 Location of Use. *An acceptable location of use specifies street address, city, state, and zip code and does not include a post office box number.*

An NRC-approved license amendment is required before receiving, using, and storing licensed material at an address or location not included with the application or already listed on the license.

Being granted an NRC license does not relieve a licensee from complying with other applicable Federal, State, or local regulations (e.g., local zoning requirements; a local ordinance requiring registration of a radiation-producing device).

Note: As discussed in Section 8.5.2, "Financial Assurance and Recordkeeping for Decommissioning," licensees do need to maintain permanent records on where licensed material was used or stored while the license was in force. This is important for making future determinations about the release of these locations for unrestricted use (e.g., before the license is terminated). Acceptable records are sketches or written descriptions of the specific locations or room numbers where special nuclear material is used or stored, and any records of spills in or around the licensee's facilities, or information relevant to damaged devices or leak test of radioactive sources.

8.4 ITEM 4: PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Identify the individual who can answer questions about the application and include his or her telephone number. This is typically the proposed RSO, unless the applicant has named a different person as the contact. NRC will contact this individual if there are questions about the application.

Notify NRC if the contact person or his or her telephone number changes so that NRC can contact the applicant or licensee in the future with questions, concerns, or information. This notice is for "information only" and does not require a license amendment or a fee.

As indicated on NRC Form 313 (Appendix B), Items 5 through 11 should be submitted on separate sheets of paper. Applicants may use Appendix C for this purpose and should note that using the suggested wording of responses and committing to using the model procedures in this report will expedite NRC's review.

8.5 ITEM 5: RADIOACTIVE MATERIAL

8.5.1 SEALED SOURCES AND DEVICES OR UNSEALED RADIOACTIVE MATERIAL

Regulations: 10 CFR 70.14; 10 CFR 70.22; 10 CFR 70.23; 10 CFR 70.39.

Criteria: An application for a license will be approved if the requirements of 10 CFR 70.23 are met. In addition, licensees will be authorized to possess and use only those sealed sources and devices that are specifically approved or registered by NRC or an Agreement State.

Discussion: Each authorized radioisotope is listed on the NRC license by its element name, chemical and/or physical form, and the maximum possession limit, as shown in the sample license in Appendix N. Table 8.1 below shows the type of radioactive material covered by this report.

Table 8.1 Types of Radioactive Materials.

Type of Material	Covered by This Report	Examples
Byproduct (reactor-produced)	No	H-3, C-14, I-131, I-125, S-35, P-32, P-33, Ca-45, Ni-63, Cd-109, Cs-137
Source material	No	U, Th
Special nuclear material	Yes	U-233, U-235, and Pu
Naturally occurring radioisotopes	No	Ra-226
Accelerator-produced radioisotopes	No	Co-57, Na-22, Tl-201, Ga-67

The applicant should list each requested radioisotope by its element name and its mass number [e.g., uranium-233(U-233)] in item 5. It is necessary to specify whether the material will be acquired and used in unsealed or sealed form. The name of the specific chemical compound that contains the radioisotope is not required. For volatile radioactive material, however, it is necessary to specify whether the requested radioisotope will be acquired in free (volatile) or bound (non-volatile) form, because additional safety precautions are required when handling and using free form volatile material.

Applicants requesting an authorization to use volatile radioactive material must provide appropriate facilities, engineering controls, and radiation safety procedures for handling of such material.

The anticipated possession limit in milligrams (mg) or grams (g) for each radioisotope should also be specified. Possession limits must cover the total anticipated inventory, including licensed material in storage and waste, and should be commensurate with the applicant's needs and facilities for safe handling. Applicants should review the requirements for submitting a certification for financial assurance for decommissioning before specifying possession limits of any radioisotope with a half-life greater than 120 days. These requirements are discussed in Section 8.5.2, "Financial Assurance and Recordkeeping for Decommissioning."

Requests to license naturally-occurring radioactive material (NORM) and accelerator-produced radioactive material should be made to the appropriate state regulatory agency. NRC does not regulate NORM or accelerator-produced radioactive material.

A safety evaluation of sealed sources and devices is performed by NRC or an Agreement State before authorizing a manufacturer (or distributor) to distribute them to specific licensees. The safety evaluation is documented in a Sealed Source and Device (SSD) Registration Certificate. Information on SSD registration certificates may be obtained by contacting the Registration Assistant by calling NRC's toll-free number (800) 368-5642, extension 415-7231. Before the formalization of the SSD registration process, some older sources or devices may have been

formalization of the SSD registration process, some older sources or devices may have been specifically approved on a license. Licensees can continue to use those sources and devices specifically listed on their licenses. Applicants must provide the manufacturer's name and model number for each requested sealed source and device so that NRC can verify that they have been evaluated in an SSD Registration Certificate or specifically approved on a license. See also NUREG-1556, Vol. 3, "Consolidated Guidance on Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration."

Consult with the proposed supplier, manufacturer, or distributor to ensure that requested sources and devices are compatible with and conform to the sealed source and device designations registered with NRC or an Agreement State. Licensees may not make any changes to the sealed source, device, or source/device combination that would alter the description or specifications from those indicated in the respective registration certificates, without obtaining NRC's prior permission in a license amendment. To ensure that applicants use sources and devices according to the registration certificates, they may want to get a copy of the certificate and review it or discuss it with the manufacturer.

Response from Applicant:

For unsealed materials:

— Provide element name with mass number, chemical and/or physical form, and maximum requested possession limit.

For potentially volatile materials:

— Specify whether the material will be free (volatile) or bound (non-volatile) and the requested possession limit for each form.

For sealed materials:

— Identify each radionuclide (element name and mass number) that will be used and specify the maximum quantity (mass) per source. Also, specify the maximum number of sources or total quantity for each radionuclide;

— Provide the manufacturer's (distributor's) name and model number for each sealed source and device requested;

— Confirm that each sealed source, device, and source/device combination is registered as an approved sealed source or device by NRC or an Agreement State;

— Confirm that the activity per source and maximum quantity in each device will not exceed the maximum quantity listed on the approved certificate of registration issued by NRC or by an Agreement State.

Provide an Emergency Plan (if required).

8.5.2 FINANCIAL ASSURANCE AND RECORDKEEPING FOR DECOMMISSIONING

Regulations: 10 CFR 30.35; 10 CFR 70.25; 10 CFR 70.51(b)(6).

Criteria: A licensee authorized to possess licensed material in excess of the limits specified in 10 CFR 30.35 and 70.25 must submit a decommissioning funding plan (DFP) or provide a certification of financial assurance (F/A) for decommissioning. All licensees are required to maintain records of information important to the decommissioning of the facility in an identified location until the site is released for unrestricted use. Licensees must transfer these records either to the new licensee before licensed activities are transferred or assigned in accordance with 10 CFR 70.51(b)(6), or to the appropriate NRC Regional Office before the license is terminated.

Financial Assurance

Discussion: NRC regulations requiring an F/A and/or a DFP are designed to provide reasonable assurance that the technical and environmental components of decommissioning are carried out and unrestricted use of the facilities is possible at the conclusion/termination of licensed activities. These requirements, if applicable, specify that a licensee either set aside funds for decommissioning activities or provide a guarantee through a third party that funds will be available (see Figure 8.2). Applicants are required to submit an F/A and/or a DFP when the license authorizes possession of radioactive material of half-life (T1/2) greater than 120 days and exceeds certain limits. Criteria for determining whether an applicant is required to submit a DFP and/or an F/A (or neither) are stated in 10 CFR 70.25.

NRC wants to ensure that decommissioning will be carried out with minimum impact on the public, occupational health and safety, and the environment (53 FR 24018). There are two parts to this rule: financial assurance that applies to *some* licensees, and recordkeeping that applies to *all* licensees.

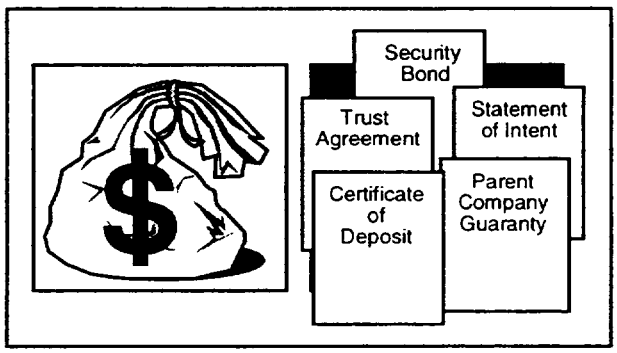

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Figure 8.2 Methods of Certification of Financial Assurance for Decommissioning.

Regulatory Guide (RG) 3.66, "Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70, and 72," dated June 1990, contains approved wording for each mechanism authorized by the regulation to guarantee or secure funds except for the Statement of Intent for government licensees.

Recordkeeping

The requirements for maintaining records important to decommissioning, including the type of information required, are stated in 10 CFR 70.25(g). All licensees are required to maintain these records in an identified location until the site is released for unrestricted use (see Figure 8.3). In the event that the licensed activities are transferred to another person or entity, these records shall be transferred to the new licensee prior to transfer of the licensed activities. The new licensee is responsible for maintaining these records until the license is terminated. When the license is terminated, these records shall be transferred to NRC.

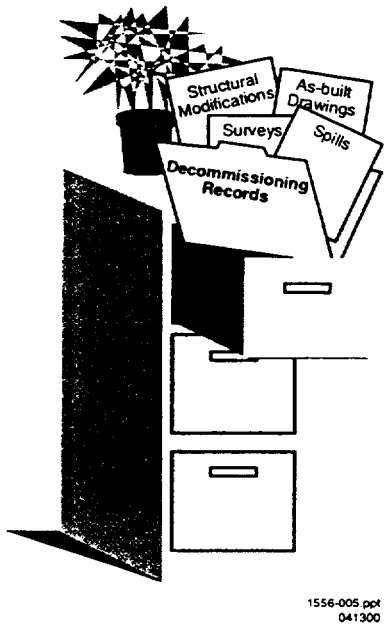


Figure 8.3 Types of Records That Must Be Maintained for Decommissioning.

10 CFR 70.25(g), Requirements for Disposition of Records Important to Decommissioning

- Before licensed activities are transferred or assigned according to 10 CFR 70.42(b), transfer to the new licensee;

OR

- Before the license is terminated, transfer records to the appropriate NRC Regional Office.

Response from Applicants: No response is needed from most applicants requesting only sealed sources. If an F/A and/or a DFP is required, submit the required documents as described in Regulatory Guides 3.65 and 3.66.

References: See the Notice of Availability on the inside front cover of this report to obtain copies of these documents:

- Regulatory Guide 3.65, "Standard Format and Content of Decommissioning Plans for Licensees Under 10 CFR Parts 30, 40, and 70," dated August 1989;
- Regulatory Guide 3.66, "Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70, and 72," dated June 1990.

Additional Reference:

- Policy and Guidance Directive FC 90-2 (Revision. 1), "Standard Review Plan for Evaluating Compliance with Decommissioning Requirements," dated April 30, 1991.

8.6 ITEM 6: PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED

Regulations: 10 CFR 70.23(a)(1); 10 CFR 70.4.

Criteria: Requested radioisotopes must be authorized by the Atomic Energy Act of 1954, as amended. All sealed sources and devices containing licensed material shall be used only for the purpose for which they are designed, and according to manufacturer's (distributor's) instructions and recommendations for use as specified in the SSD Registration Certificate.

Discussion: Applicants should clearly specify the purpose for which each radioisotope will be used and a general plan for carrying out the activity should be described. Each individual use should be described.

The typical license authorizes persons to perform research and development and student instruction using Pu-Be sealed sources in a neutron howitzer, experiments utilizing sub-critical assemblies, and calibration of radiation detection instruments. Non-typical uses will be evaluated on a case-by-case basis and the authorized use condition will reflect approved uses.

The described uses should contain sufficient information to enable the reviewers to have a clear understanding of each use and determine the potential for exposure of workers and members of the public to radiation and radioactive materials.

Response from Applicant: List the specific use or purpose of each radioisotope.

8.7 ITEM 7: INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE

8.7.1 RADIATION SAFETY OFFICER (RSO)

Regulations: 10 CFR 70.23(a)(2).

Criteria: Radiation Safety Officers must have training and specific experience appropriate for the types and quantities of licensed material to be authorized on the license.

Discussion: The person responsible for implementing the radiation protection program is called the Radiation Safety Officer (RSO), or the Radiation Protection Officer (RPO). The RSO needs independent authority to stop operations that he or she considers unsafe. He or she must have sufficient time and commitment from management to fulfill certain duties and responsibilities to ensure that radioactive materials are used in a safe manner. Typical RSO duties are illustrated in Figure 8.4 and described in Appendix E.

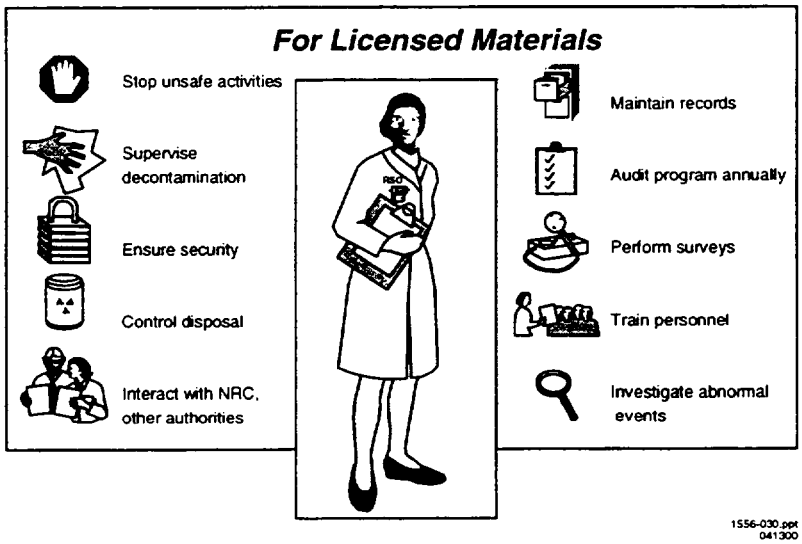


Figure 8.4 RSO Responsibilities. *Typical duties and responsibilities of RSOs.*

NRC believes that to demonstrate adequate training and experience, the RSO should have: (1) sufficient knowledge of physical, chemical, biological sciences, or engineering; and (2) training and experience commensurate with the scope of proposed activities. Training should include the following subjects:

- Radiation protection principles;
- Characteristics of ionizing radiation;
- Units of radiation dose and quantities;

- Radiation detection instrumentation;
- Biological hazards of exposure to radiation (appropriate to types and forms of special nuclear material to be used);
- NRC regulatory requirements and standards;
- Hands-on use of radioactive materials.

The length of training and experience described above, will depend upon the type, form, quantity, and proposed use of the licensed material requested. Ultimately, the proposed RSO's training and experience should be sufficient to identify and control the anticipated radiation hazards.

Response from Applicant: Provide the following:

- Name of the proposed RSO;
- Information demonstrating that the proposed RSO is qualified by training and experience.

Applicants should provide information about the proposed RSO's training and experience relative to the licensed material requested in the application. Applicants should not submit extraneous information such as unrelated lists of publications, research grants, committee and society memberships, etc. Submittal of unrelated material serves only to slow the review process.

Note: It is required to notify NRC of changes in the designation of the RSO. The name and qualifications of the replacement RSO must be submitted to NRC as part of an amendment request.

8.7.2 AUTHORIZED USERS

Regulations: 10 CFR 20.1101(b); 10 CFR 70.23(a)(2).

Criteria: Authorized users (AUs) must have adequate training and experience with the types and quantities of licensed material that they propose to use.

Discussion: An AU (also known as "principal investigator") is a person whose training and experience have been reviewed and approved by NRC, who is named on the license, and who uses or directly supervises the use of licensed material. The AU's primary responsibility is to ensure that radioactive materials used in his or her particular lab or area are used safely and according to regulatory requirements (See Figure 8.5). The AU is also responsible to ensure that procedures and engineering controls are used to keep occupational doses and doses to members of the public ALARA.

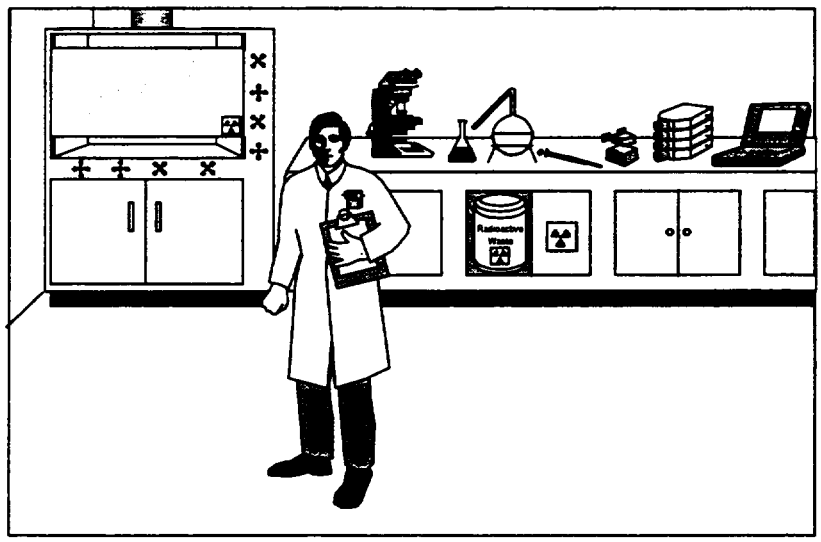


Figure 8.5 Authorized User. *The Authorized User is responsible for the safe use of licensed material in his or her laboratory or area.*

AUs must have adequate and appropriate training to provide reasonable assurance that they will use licensed material safely, including maintaining security of, and access to, licensed material, and respond appropriately to events or accidents involving licensed material to prevent the spread of contamination.

NRC believes that to demonstrate adequate training and experience the AU should have: (1) sufficient knowledge of physical, chemical, biological sciences, or engineering; and (2) training and experience commensurate with the scope of proposed activities. Training should include the following topics:

- Radiation protection principles;
- Characteristics of ionizing radiation;
- Units of radiation dose and quantities;
- Radiation detection instrumentation;
- Biological hazards of exposure to radiation (appropriate to the types and forms of special nuclear material to be used);
- Hands-on use of radioactive materials.

The length of training and experience described above will depend upon the type, form, quantity, and proposed use of the licensed material requested.

An AU is considered to be supervising the use of radioactive materials when he or she directs personnel in operations involving the licensed material. Although the AU may delegate specific

tasks to supervised users (e.g., conducting surveys, keeping records), he or she is responsible for the safe use of radioactive material to assure that areas are not contaminated.

Applicants must name at least one qualified authorized user. In general, AUs must demonstrate training and experience with the type and quantity of material that they propose to use. For example, someone with training and experience only with sealed radioactive sources may not be qualified to use or supervise the use of unsealed licensed material. In addition, someone with experience using only trace quantities may not understand the risks of working with much larger (e.g., 10 or more times larger) quantities of the same substance. Applicants should pay particular attention to the type of radiation involved. For example, someone experienced with gamma emitters may not have appropriate experience for high energy beta emitters.

Response from Applicant: Provide the following:

- Name of each proposed AU with the types and quantities of licensed material to be used;
- Information demonstrating that each proposed AU is qualified by training and experience to use the requested licensed materials.

Applicants should provide information about the proposed AU's training and experience relative to the licensed material requested in the application. Applicants should not submit extraneous information, such as unrelated lists of publications, research grants, committee and society memberships, etc. Submittal of unrelated material serves only to slow the review process.

8.8 ITEM 8: TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS (INSTRUCTIONS TO OCCUPATIONALLY EXPOSED WORKERS AND ANCILLARY PERSONNEL)

Regulations: 10 CFR 19.11; 10 CFR 19.12; 10 CFR 19.13; 10 CFR 70.7; 10 CFR 70.10; 10 CFR 70.23(a)(2).

Criteria: Individuals whose assigned duties involve exposure to radiation and/or radioactive material (from both licensed and unlicensed sources), and in the course of their employment are likely to receive in a year an occupational dose of radiation greater than 1 mSv (100 mrem), must receive instruction commensurate with their duties and responsibilities, as required by 10 CFR 19.12.

Discussion: Before beginning work with licensed material, individuals must receive radiation safety training commensurate with their assigned duties and specific to the licensee's radiation safety program. Each individual should also receive periodic refresher training.

Licensees should not assume that safety instruction has been adequately covered by prior employment or academic training. Site-specific training should be provided for all individuals. Particular attention should be given to persons performing work with radioactive materials that may require special procedures, such as hot cell work and waste processing. Also, ancillary personnel (e.g., clerical, housekeeping, security), whose duties may require them to work in the vicinity of radioactive material (whether escorted or not), need to be informed about radiation hazards and the appropriate precautions. The licensee should assess each individual's involvement with licensed material and cover each applicable subject appropriately.

Training may be in the form of lecture, demonstrations, videotape, or self-study, and should emphasize practical subjects important to the safe use of licensed material. The program should consider both the topics pertinent for each group of workers and the method and frequency of training.

The person conducting the training should be a qualified individual (e.g., a person who meets the qualifications for RSO or authorized user on the license and is familiar with the licensee's program).

Response from Applicant: A description of the radiation safety training program, including topics covered, groups of workers, assessment of training, qualifications of instructors, and the method and frequency of training.

8.9 ITEM 9: FACILITIES AND EQUIPMENT

Regulations: 10 CFR 20.1101(b); 10 CFR 20.1406; 10 CFR 70.22(a)(7); 10 CFR 70.23(a)(3); 10 CFR 70.25(g); 10 CFR 70.41(a).

Criteria: Facilities and equipment must be adequate to protect health and minimize danger to life and property.

Discussion: Applicants must demonstrate that their facilities and equipment provide sufficient engineering controls and barriers to protect the health and safety of the public and its employees, keep exposures to radiation and radioactive materials ALARA, and minimize the danger to life and property from the uses of the types and quantities of radioactive materials to be used.

Applicants may delay completing facilities and acquiring equipment until after the application review is completed, in case changes are required as a result of the application review. This also ensures the adequacy of the facilities and equipment before the applicant makes a significant financial commitment. In all cases, the applicant cannot possess or use licensed material until after the facilities are approved and completed, equipment is procured and ready for use, and the license is issued.

Applicants are reminded that records important to decommissioning include the following:

- As-built drawings and modifications of structures and equipment in restricted areas;
- As-built drawings and modifications of locations of possible inaccessible contamination such as buried pipes that may be subject to contamination;
- Records of spills and unusual occurrences that may result in contamination of the facility or site.

These records are required to be maintained in an identifiable location. Facilities are required to meet NRC criteria prior to release. Therefore, careful facility design is important to prevent contamination, facilitate decontamination, and reduce the costs needed for decommissioning. For further information, see Section 8.5.2, "Financial Assurance and Recordkeeping for Decommissioning."

For additional guidance regarding facilities and equipment, refer to Appendix F.

Response from Applicant: Describe the facilities and equipment to be made available at each location where radioactive material will be used. Include a description of the area(s) assigned for the receipt, storage, security, preparation, and measurement of radioactive materials. A diagram should be submitted showing the locations of shielding, the proximity of radiation sources to unrestricted areas, and other items related to radiation safety. When applicable to facilities where radioactive materials may become airborne, the diagrams should contain schematic descriptions of the ventilation systems, with pertinent airflow rates, pressures, filtration equipment, and monitoring systems. Diagrams should be drawn to a specified scale, or dimensions should be indicated. For facilities where it is anticipated that more than one laboratory or room may be used, a generic laboratory or room diagram may be submitted.

8.10 ITEM 10: RADIATION SAFETY PROGRAM

8.10.1 AUDIT PROGRAM

Regulations: 10 CFR 20.1101; 10 CFR 20.2102; 10 CFR 21.21(a).

Criteria: Licensees must review the content and implementation of their radiation protection programs at least annually to ensure the following:

- Compliance with NRC and DOT regulations (as applicable), and the terms and conditions of the license;
- Occupational doses and doses to members of the public are ALARA (10 CFR 20.1101); and
- Records of audits and other reviews of program content are maintained for 3 years.

Discussion: Appendix G contains a suggested audit program that is applicable to special nuclear material of less than critical mass licensees and is acceptable to NRC. However, all areas indicated in Appendix G may not be applicable to every licensee and may not need to be addressed during each audit. For example, licensees do not need to address areas which do not apply to their activities, and activities which have not occurred since the last audit. Generally, audits are conducted at least once every 12 months to meet the annual requirement.

Currently, NRC's emphasis in inspections is to perform actual observations of work in progress. As a part of their audit programs, applicants should consider performing unannounced audits of licensed material users to determine if, for example, Safe Use and Emergency Procedures are available and are being followed.

If an audit identifies violations of NRC requirements, the licensee should first evaluate the safety significance of each violation to set priorities and identify resources to correct these violations. IN 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," dated May 1, 1996, provides guidance on this subject. Certain identified problems or potential violations may require notification or a report to NRC. Licensees are encouraged to contact NRC for guidance if there is any uncertainty regarding a reporting requirement. NRC routinely reviews licensee's records to verify if appropriate corrective actions were implemented in a timely manner to prevent recurrence. It is in the best interest of the licensee to identify potential violations of regulatory requirements and take necessary steps to correct them. NRC can exercise discretion and may elect not to cite the licensee for these violations if prompt and effective corrective actions are implemented. For information on NRC's use of discretion on issuing a notice of violation, refer to "General Statement of Policy and Procedures for NRC Enforcement Actions" (NUREG-1600).

Licensees must maintain records of these audits and other reviews of program content and implementation for 3 years from the date of the record. Records of these audits should include the following information: date of audit, name of person(s) who conducted audit, persons contacted by the auditor(s), areas audited, audit findings, corrective actions, and follow-up. These records must be maintained for inspections by NRC.

Response from Applicant: The applicant is not required to, and should not, submit its audit program to NRC for review during the licensing phase. However, this information may be reviewed during NRC inspections.

References: See the Notice of Availability on the inside front cover of this report to obtain copies of:

- Inspection Procedure 87110, Appendix A, "Industrial/Academic/Research Inspection Field Notes," dated February 3, 1997;
- NUREG-1600, "General Statement of Policy and Procedures on NRC Enforcement Actions" ;

- Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," dated May 1, 1996.

Inspection Procedure 87110, NUREG-1600, and Information Notice 96-28 are available on the Internet at <http://www.nrc.gov>.

8.10.2 RADIATION MONITORING INSTRUMENTS

Regulations: 10 CFR 20.1501; 10 CFR 20.2103(a); 10 CFR 70.23(a)(3).

Criteria: Licensees must possess, or have access to, radiation monitoring instruments that are necessary to protect health and minimize danger to life or property. Instruments used for quantitative radiation measurements must be calibrated periodically for the radiation measured.

Discussion: Licensees shall possess, or have access to, calibrated radiation detection/measurement instruments or licensed services to perform, as necessary, the following:

- Package surveys;
- Contamination surveys;
- Sealed source leak tests;
- Air sampling measurements;
- Bioassay measurements;
- Effluent release measurements;
- Unrestricted area dose rate measurements.

For the purposes of this document, survey instruments are defined as any device used to measure the radiological conditions at a licensed facility. Some of the survey instruments that may be used to perform the above functions include:

- Portable or stationary count rate meters;
- Portable or stationary dose rate or exposure rate meters;
- Single or Multichannel Analyzers;
- Liquid Scintillation Counters (LSC);
- Gamma Counters;
- Proportional Counters;
- ZnS Detectors;
- Neutron Detectors;
- Solid State Detectors.

The choice of instrument should be appropriate for the type of radiation to be measured, and for the type of measurement to be taken (e.g., count rate, dose rate, etc.). The majority of the radioactive emissions from special nuclear material are alpha emissions, therefore the applicant's instrumentation should include instrumentation capable of detecting alpha emissions, such as ZnS detectors. Applications should include descriptions of the instrumentation available for use, and any instrumentation applicants intend to purchase prior to starting licensed activities. The description should include type of instrument and probe, and the instrument's intended purpose.

Instruments used for qualitative surveys are only intended to detect contamination in the laboratory. Such instruments should be checked for operational response with an appropriate check source containing radioactive material, and can be calibrated with an electronic pulser instead of a radioactive source. However, these instruments cannot be used for *measurement* of surface contamination or radiation levels without a calibration with appropriate radioactive sources.

NRC requires that calibrations be performed by the instrument manufacturer or a person specifically authorized by NRC or an Agreement State, unless the applicant specifically requests this authorization. Applicants seeking authorization to perform survey instrument calibrations shall submit procedures for review. Appendix H provides information about instrument specifications and model calibration procedures.

Response from Applicant: Provide one of the following:

A description of the instrumentation (as described above) that will be used to perform required surveys and a statement that: "We will use instruments that meet the radiation monitoring instrument specifications published in Appendix H to NUREG-1556, Vol. 17, 'Program-Specific Guidance About Special Nuclear Material of Less Than a Critical Mass Licenses,' dated November 2000. We reserve the right to upgrade our survey instruments as necessary."

OR

A description of the instrumentation (as described above) that will be used to perform required surveys and a statement that: "We will use instruments that meet the radiation monitoring instrument specifications published in Appendix H to NUREG-1556, Vol. 17, 'Program-Specific Guidance About Special Nuclear Material of Less Than a Critical Mass Licenses,' dated November 2000. Additionally, we will implement the model survey meter calibration program published in Appendix H to NUREG-1556, Vol. 17, 'Program-Specific Guidance About Special Nuclear Material of Less Than a Critical Mass Licenses,' dated November 2000. We reserve the right to upgrade our survey instruments as necessary."

OR

A description of alternative equipment and/or procedures for ensuring that appropriate radiation monitoring equipment will be used during licensed activities and that proper calibration and calibration frequency of survey equipment will be performed. Further, the

statement "We reserve the right to upgrade our survey instruments as necessary" should be added to the response.

Note: Alternative responses will be reviewed using the criteria listed above.

8.10.3 MATERIAL RECEIPT AND ACCOUNTABILITY

Regulations: 10 CFR 20.1501(a); 10 CFR 20.1801; 10 CFR 20.1802; 10 CFR 20.1906; 10 CFR 20.2001; 10 CFR 20.2201; 10 CFR 70.22(a)(8); 10 CFR 70.23(a)(4); 10 CFR 70.25(g); 10 CFR 70.51; 10 CFR 70.54; 10 CFR 74.15; 10 CFR 75.34.

Criteria: Licensees must do the following:

- Develop, implement, and maintain written procedures for safely opening packages;
- Develop, implement, and maintain procedures to ensure control and accountability of licensed material;
- Maintain records of receipt, transfer, and disposal of licensed material.

Discussion: Licensees are required to develop, implement, and maintain written procedures for safely opening packages in accordance with 10 CFR 20.1906. Some packages may require special procedures that take into consideration the type, quantity, or half-life of the nuclide being delivered.

SNM licensees should provide their Reporting Identification Symbol (RIS) to their supplier when ordering amounts of one effective gram or more of SNM. An RIS can only be obtained after the NRC license is issued. Once the license is issued, the licensee should call NRC at (800) 368-5642 and ask for the Division of Fuel Cycle Safety and Safeguards, Regulatory and International Safeguards Branch. In order to process the request to be assigned an RIS the following information will be requested: NRC License Number, address where the material will be used and stored, business address of the licensee, and name and telephone number of a contact person.

Licensees need to make arrangements to receive radioactive packages when they are delivered or to be notified when radioactive packages arrive at the carrier's terminal so that the licensee can pick up the package expeditiously.

In limited scope radiation safety programs, the RSO or his/her staff usually receives the incoming package directly from the carrier, and performs all verification, surveying, opening, and documentation for inventory. The package is then delivered to the AU, or the AU retrieves the package from the RSO. If the package is transported over public roads by the licensee, it must be repackaged and transported in accordance with DOT regulations.

If the package of licensed material is delivered to the licensed facility's receiving department (Receiving), individuals working in that department should be trained to do the following:

- Identify the package as containing radioactive material by labeling and shipping papers;
- Segregate the package from other incoming items in a secured area until released by the RSO;
- Notify the RSO.

When notified by Receiving that a package of licensed material has arrived, the RSO or his/her staff should retrieve the package and follow the safe opening procedures.

NRC regulations in 10 CFR 20.1906(b) and (c) state the requirements for monitoring packages containing licensed material. These requirements are described in Table 8.2, below.

Table 8.2 Package Monitoring Requirements.

Package Contents	Survey Type	Survey Time*
Labeled (White I, Yellow II, Yellow III)	Gas or Special Form Greater Than Type A	Radiation Level	As soon as practicable, but not later than 3 hours after receipt of package
Labeled (White I, Yellow II, Yellow III)	Not Gas Nor Special Form Greater Than Type A	Contamination Radiation Level	As soon as practicable, but not later than 3 hours after receipt of package
Labeled (White I, Yellow II, Yellow III)	Gas or Special Form Less Than Type A	None	None
Labeled (White I, Yellow II, Yellow III)	Not Gas Nor Special Form Less Than Type A	Contamination	As soon as practicable, but not later than 3 hours after receipt of package
Not Labeled	Licensed Material	None	None
Damaged	Licensed Material	Contamination Radiation Level	As soon as practicable, but not later than 3 hours after receipt of package

* Assumes packages are received during normal working hours. If packages are received outside of normal working hours, the licensee has three hours after the beginning of the next work day to perform the required surveys.

10 CFR 20.1906(d) requires that the licensee immediately notify the final delivery carrier and, by telephone, telegram, mailgram, or facsimile, the Administrator of the appropriate NRC Regional Office listed in Appendix D to 10 CFR Part 20 when removable radioactive surface contamination exceeds the limits of 10 CFR 71.87(i); or external radiation levels exceed the limits of 10 CFR 71.47.

As illustrated in Figure 8.6, licensed materials must be tracked from "receipt to disposal" in order to ensure accountability and to ensure that possession limits listed on the license are not exceeded.

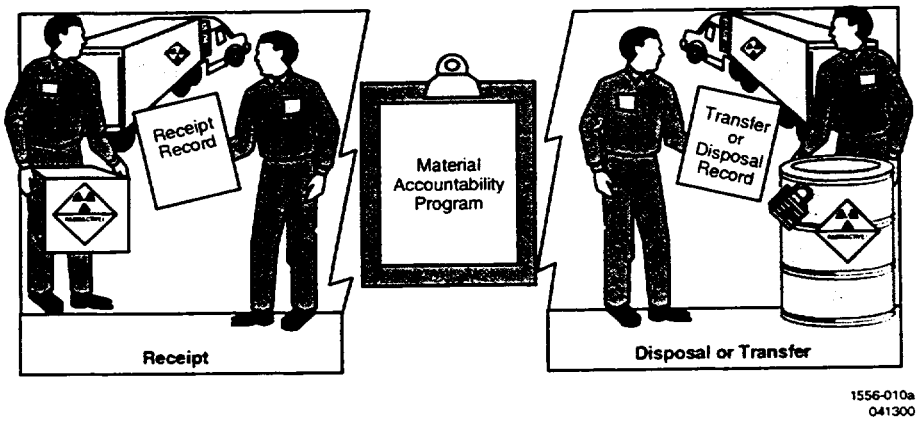


Figure 8.6 Material Receipt and Accountability. *Licensees must maintain records of receipt, transfer, and disposal of licensed material.*

It is recognized that loss, theft, or misplacement of licensed material can occur; however, licensees must have in place an accountability and control system for promptly detecting losses of licensed material.

Licensees who use and/or possess sealed sources are required by license condition to perform inventories of sealed sources every six months (see Sample License, Condition No. 16). Some sealed sources may not be in use or are rarely used and are placed in storage. In these cases, licensees should confirm that these sealed sources have not been disturbed at least every 6 months. Licensees are also required to conduct leak tests of sealed sources at 6-month intervals (or at longer intervals as specified in the SSD Registration Certificate). Since the leak tests require an individual to locate and work with the sealed source, records of leak tests may be used as part of an inventory and accountability program.

With regard to unsealed licensed material, licensees use various methods (e.g., computer programs, manual ledgers, log books) to account for receipt, use, transfer, disposal, and radioactive decay. These methods help to ensure that possession limits are not exceeded.

SNM licensees are required by 10 CFR 70.54 to comply with 10 CFR 74.15 and 10 CFR 75.34. These regulations require licensees to submit DOE/NRC Form 741. NUREG/BR-0006 Revision 3, "Instructions for Completing Nuclear Material Transaction Reports and Concise Note Forms," provides step-by-step instructions for filling out the form.

To ensure that only trained, experienced, and authorized individuals use or supervise the use of licensed material, the RSO should know who has requested an order of licensed material and the types and amounts of licensed materials requested. Control procedures should also be established for the procurement of licensed materials that may be obtained outside the normal channels, e.g., through the loan or other transfer of materials without purchase or through surplus.

NRC regulations applicable to transfers are stated in 10 CFR 70.42. Transfer of licensed materials within the facility may require special procedures to ensure proper control. In many facilities, pieces of laboratory equipment or components including refrigerators and freezers will become contaminated. Removal of these items for maintenance, repair, or disposal should also be carefully controlled.

Licensees must maintain records of receipt, use, transfer, and disposal (as waste) of all licensed material. Table 8.3 below lists each type of record and how long the record must be maintained. Other records such as transfer records could be linked to radioactive material inventory records. Receipt records should also document cases where excessive radiation levels or radioactive contamination were found on packages or containers of material received and describe the action taken. NUREG-1460, Revision 1, "Guide to NRC Reporting and Recordkeeping Requirements," dated July 1994, provides additional information.

Table 8.3 Record Maintenance.

Type of Record	How Long Record Must be Maintained
Receipt	For as long as the material is possessed until 3 years after transfer or disposal
Transfer	For 3 years after transfer
Disposal	Until NRC terminates the license
Decommissioning	Until the site is released for unrestricted use

Receipt, transfer, and disposal records typically contain the following information:

- Radionuclide and quantity, and date of measurement of special nuclear material;
- For each sealed source, manufacturer, model number, location, and, if needed for identification, serial number and as appropriate, manufacturer and model number of device containing the sealed source;
- Date of the transfer and name and license number of the recipient, and description of the affected radioactive material (e.g., radionuclide, quantity, manufacturer's name and model number, serial number);
- For licensed materials disposed of as waste, include the radionuclide, quantity, date of disposal, and method of disposal (decay, sewer, etc.).

See the Section 8.11, "Waste Management," for additional information.

Information about locations where licensed material is used or stored are among the records important to decommissioning and required by 10 CFR 70.25(g). Also see Section 8.5.2, "Financial Assurance and Recordkeeping for Decommissioning."

Response from Applicant:

- Develop a procedure(s) for ensuring material accountability.

AND

- Provide either of the following:
  - — A statement that: "Physical inventories will be conducted at intervals not to exceed 6 months, to account for all sealed sources and devices received and possessed under the license."

OR

  - — A description of procedures for ensuring that no sealed sources have been lost, stolen, or misplaced and how often this will be done.

***Note*:**

- No response is needed from applicants for package opening procedures. Package opening procedures will be reviewed during NRC inspections.
- Alternative responses will be evaluated using the criteria listed above.

References:

See the Notice of Availability on the inside front cover of this report to obtain a copy of:

- NUREG-1460, Revision 1, "Guide to NRC Reporting and Recordkeeping Requirements," dated July 1994;
- NUREG/BR-0006, Revision 3, "Instructions for Completing Nuclear Material Transaction Reports and Concise Note Forms";
- Many NRC documents can be accessed at the following Internet address: <http:\\www.nrc.gov>.

8.10.4 OCCUPATIONAL DOSE

Regulations: 10 CFR 20.1101; 10 CFR 20.1201; 10 CFR 20.1202; 10 CFR 20.1203; 10 CFR 20.1204; 10 CFR 20.1207; 10 CFR 20.1208; 10 CFR 20.1501; 10 CFR 20.1502; 10 CFR 20.1703; 10 CFR 20.2106; 10 CFR 20 Appendix B.

Criteria: The use of individual monitoring devices for external dose is required for:

- Adults who are likely to receive an annual dose in excess of any of the following (each evaluated separately):
  - — 5 mSv (0.5 rem) deep-dose equivalent;
  - — 15 mSv (1.5 rems) eye dose equivalent;
  - — 50 mSv (5 rems) shallow-dose equivalent to the skin;
  - — 50 mSv (5 rems) shallow-dose equivalent to any extremity;
- Minors who are likely to receive an annual dose in excess of any of the following (each evaluated separately):
  - — 1.0 mSv (0.1 rem) deep-dose equivalent;
  - — 1.5 mSv (0.15 rem) eye dose equivalent;
  - — 5 mSv (0.5 rem) shallow-dose equivalent to the skin;
  - — 5 mSv (0.5 rem) shallow-dose equivalent to any extremity;
- Pregnant women who are likely to receive an annual dose from occupational exposures in excess of 1.0 mSv (0.1 rem) deep-dose equivalent, although the dose limit applies to the entire gestation period;
- Individuals entering a high or very high radiation area.

Internal exposure monitoring (not necessarily individual monitoring devices) is required for:

- Adults likely to receive in 1 year an intake in excess of 10% of the applicable ALIs for ingestion and inhalation;
- Minors and declared pregnant women likely to receive in 1 year a committed effective dose equivalent in excess of 1.0 mSv (0.1 rem).

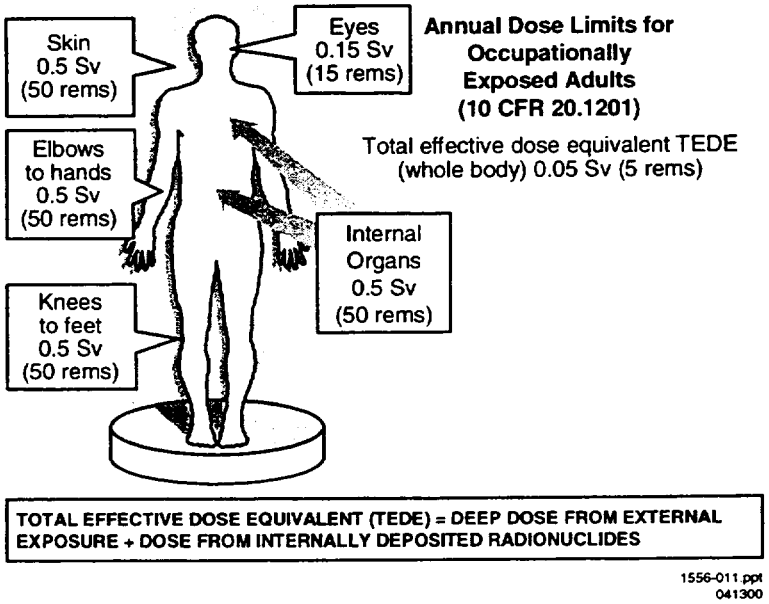


Figure 8.7 Annual Dose Limits for Occupationally Exposed Individuals.

Discussion:

TOTAL EFFECTIVE DOSE EQUIVALENT (TEDE) = DEEP DOSE FROM EXTERNAL EXPOSURE + DOSE FROM INTERNALLY DEPOSITED RADIONUCLIDES

According to 10 CFR 20.1502, if an adult (individual) is likely to receive in 1 year a dose greater than 10% of any applicable limit (See Figure 8.7 for annual dose limits), monitoring for occupational exposure is required. The licensee should perform an evaluation of the dose the individual is likely to receive prior to allowing the individual to receive the dose. This evaluation need not be made for every individual; evaluations can be made for employees with similar job functions or work areas. Further guidance on evaluating the need to provide monitoring is provided in Appendix I of this report and Regulatory Guide 8.34, "Monitoring Criteria and Methods to Calculate Occupational Doses," dated July 1992.

If this prospective evaluation shows that the individual's dose is not likely to exceed 10% of any applicable regulatory limit, there are no recordkeeping or reporting requirements. For individuals who have received doses at other facilities in the current year, the previous dose need not be considered in this prospective evaluation. When determining the need for monitoring, only a dose that could be received at the facilities of the applicant or licensee performing the evaluation needs to be considered, including any recordkeeping and reporting requirements. If an evaluation determined that monitoring was not required and a subsequent evaluation indicates that the 10% regulatory threshold may or will be exceeded, the dose received by an individual when monitoring was not provided should be estimated, recorded, and reported (if required). These estimates can be based on any combination of work location radiation monitoring, survey results, monitoring

results of individuals in similar work situations, or other estimates to produce a "best estimate" of the actual dose received.

If monitoring is not required to demonstrate compliance with all limits but is required relative to one or more specific limits, the licensee should enter "NR" in the blocks on NRC Forms 4 and 5 to indicate the areas for which monitoring was not required (e.g., extremity or skin doses). Where monitoring was provided but not measurable, the licensee should enter "ND" for "Not Detectable."

If the prospective dose evaluation shows that the individual is likely to exceed 10% of an applicable limit, monitoring is required (10 CFR 20.1502). Recordkeeping of the results of monitoring performed, regardless of the actual dose received, is required by 10 CFR 20.2106(a).

A common method for dose evaluation is to monitor workers' dose with whole body and extremity dosimetry (TLDs film, ring badge, etc.) provided by a National Voluntary Laboratory Accreditation Program (NVLAP)-approved dosimetry service. Workers are typically monitored for a year or more to determine actual annual dose. The monitoring results are then used to determine the need to continue monitoring workers. The dose to workers may need to be reevaluated if there are changes to the licensee's program, such as procedures, frequency of use, quantity of licensed material used, isotopes used, etc.

For guidance about methodologies for determination of internal occupational dose and summation of occupational dose, refer to Regulatory Guide 8.34, "Monitoring Criteria and Methods to Calculate Occupational Doses," dated July 1992, and Regulatory Guide 8.9, "Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program," dated July 1993. For copies of these guidance documents, contact the appropriate NRC Regional Office or access NRC's web site <www.nrc.gov>.

Response from Applicant: Provide either of the following:

- A statement that: "We have done a prospective evaluation and determined that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits in 10 CFR Part 20 or we will monitor individuals in accordance with the criteria in the section entitled 'Radiation Safety Program - Occupational Dose' in NUREG-1556, Vol. 17, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance About Special Nuclear Material of Less than Critical Mass Licenses,' dated November 2000."

OR

- A description of an alternate method for demonstrating compliance with the referenced regulations.

Note:

- Alternative responses will be evaluated using the criteria listed above.
- Some licensees choose to provide personnel dosimetry to their workers for reasons other than compliance with NRC requirements (e.g., to respond to worker requests).

References: See the Notice of Availability on the inside front cover of this report to obtain copies of:

- Regulatory Guide 8.7, Revision 1, "Instructions for Recording and Reporting Occupational Radiation Exposure Data," dated June 1992;
- Regulatory Guide 8.9, "Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program," dated July 1993;
- Regulatory Guide 8.34, "Monitoring Criteria and Methods to Calculate Occupational Radiation Doses," dated July 1992.

8.10.5 PUBLIC DOSE

Regulations: 10 CFR 20.1003; 10 CFR 20.1101; 10 CFR 20.1301; 10 CFR 20.1302; 10 CFR 20.2107.

Criteria: Licensees must ensure that licensed material will be used, transported, stored, and disposed of in such a way that members of the public will not receive more than 1 mSv (100 mrem) in one year, and the dose in any unrestricted area will not exceed 0.02 mSv (2 mrem) in any one hour, from licensed operations. In addition, licensees must strive to maintain doses to members of the public that are as low as is reasonably achievable (ALARA).

Discussion: "Public dose" is defined in 10 CFR Part 20 as "the dose received by a member of the public from exposure to radiation and/or radioactive material released by a licensee, or to any other source of radiation under the control of a licensee." Public dose excludes doses received from background radiation and from medical procedures. Whether the dose to an individual is an occupational dose or a public dose depends on the individual's assigned duties. It does not depend on the area (restricted, controlled, or unrestricted) the individual is in when the dose is received.

Figure 8.8 shows the steps to calculate the annual dose to an individual member of the public.

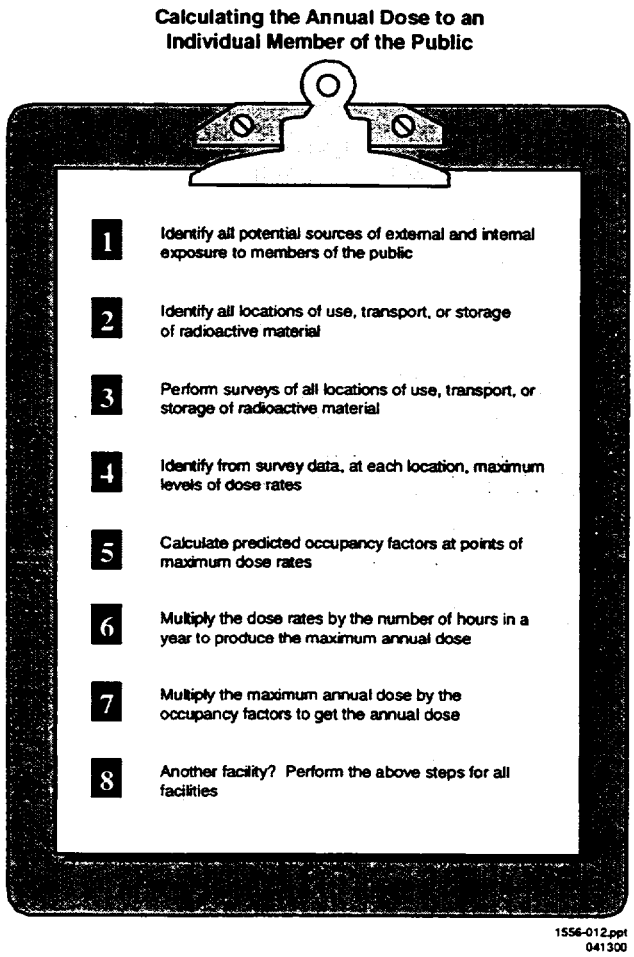


Figure 8.8 Calculating Public Dose. *Steps to calculate the annual dose to an individual member of the public (see Appendix J for more information about occupancy factors).*

There are many possible dose pathways that contribute to the TEDE. The TEDE can, however, be broken down into three major dose pathway groups:

- Airborne radioactive material;
- Waterborne radioactive material;
- External radioactive exposure.

The licensee should review these major pathways and decide which are applicable to its operations.

Licensees should design a monitoring program to ensure compliance with 10 CFR 20.1302(b). The extent and frequency of monitoring will depend upon each licensee's needs. For additional guidance regarding monitoring of effluents, refer to Section 8.10.8, "Radiation Safety Program – Surveys."

10 CFR 20.2107 requires that licensees maintain records sufficient to demonstrate compliance with the dose limits for members of the public until the Commission terminates the license. Refer to Appendix J for additional guidance regarding compliance with the recordkeeping requirements.

Response from Applicant: No response is required from the applicant in a license application, but compliance will be examined during inspection. During NRC inspections, licensees must be able to demonstrate, by measurement or calculation, that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed operation does not exceed the annual limit for members of the public.

8.10.6 OPERATING AND EMERGENCY PROCEDURES

Regulations: 10 CFR 19.11(a)(3); 10 CFR 20.1101; 10 CFR 20.1801; 10 CFR 20.1802; 10 CFR 20.2201-2203; 10 CFR 21.21; 10 CFR 70.22(a); 10 CFR 70.23(a)(4); 10 CFR 70.50.

Criteria: Each licensee must develop, implement, and maintain operating and emergency procedures that include the following provisions:

- Instructions to keep radiation doses to workers and members of public ALARA;
- Instructions for maintaining security during storage and transportation;
- Instructions to maintain accountability during use;
- Use of personnel monitoring and radiation survey equipment;
- Instructions for packaging and transporting licensed material;
- Instructions on whom to contact when an emergency occurs.

Discussion: Operating and emergency procedures should be developed, maintained, and implemented to ensure that all licensed material are used in accordance with licensed activities, control and accountability are maintained, and radiation doses received by occupational workers and members of the public are ALARA. The operating procedures should include a description of the operations involving the special nuclear material and a general plan for carrying out the activity. The written procedures should provide reasonable assurance that only appropriately trained personnel will handle and use licensed material without undue hazard to workers or members of the public. Each licensee must develop, implement, and maintain operating and emergency procedures containing the following elements:

- Contamination controls;
- Personnel and area monitoring (including frequency and limits);
- Use of protective clothing and equipment;
- Recording requirements;

- Reporting requirements;
- Waste disposal practices.

A copy of the operating and emergency procedures should be posted in all laboratory or work areas where radioactive materials are used. If posting of procedures is not practicable, the licensee may post a notice which describes the documents and states where they may be examined. Also, copies of operating and emergency procedures should be provided to all authorized users. These instructions should describe immediate action to be taken in case of an emergency in order to prevent release of radioactive material or further contamination of work areas and personnel. Examples of emergency procedures are turning off the ventilation systems, evacuation of the area, reentry, procedures for containment of spills, etc. The instructions should specifically state the names and telephones numbers of responsible persons to be notified.

NRC must be notified when licensed material is lost, stolen, or other related conditions occur. The RSO must be proactive in evaluating whether NRC notification is required. Refer to Appendix O and the regulations (10 CFR 20.2201-20.2203, 10 CFR 70.50, and 10 CFR 21.21) for a description of when and where notifications are required.

Response from Applicant: The applicant must state that procedures for safe use of materials and emergencies have been developed or will be developed before receipt of licensed material. If you want the option to make changes in the procedures, include a statement that "Procedures may be revised only if: 1) the changes are reviewed and approved by the licensee management and the RSO in writing; 2) the licensee staff is provided training in the revised procedures prior to implementation; 3) the changes are in compliance with the NRC regulations and the license; and 4) the changes do no degrade the effectiveness of the program."

8.10.7 LEAK TESTS

Regulations: 10 CFR 20.1501; 10 CFR 20.2103; 10 CFR 70.56.

Criteria: NRC requires testing to determine whether there is any radioactive leakage from the sealed sources. Records of test results must be maintained.

Discussion: When issued, a license will require performance of leak tests at intervals approved by NRC or an Agreement State and specified in the SSD Registration Certificate. The measurement of the leak-test sample is a quantitative analysis requiring that instrumentation used to analyze the sample be capable of detecting 185 Bq (0.005 microcurie) of radioactivity.

Manufacturers, consultants, and other organizations may be authorized by NRC or an Agreement State to either perform the entire leak test sequence for other licensees or provide leak test kits to licensees. In the latter case, the licensee is expected to take the leak test sample according to the kit supplier's instructions and return it to the kit supplier for evaluation and reporting results. Leak test samples should be collected at the most accessible area where contamination would

accumulate if the sealed source were leaking. Licensees may also be authorized to conduct the entire leak test sequence themselves.

Response from Applicant: Do one of the following:

- State: "Leak tests will be performed at intervals approved by NRC or an Agreement State and specified in the Sealed Source and Device Registration Certificate. Leak tests will be performed by an organization authorized by NRC or an Agreement State to provide leak testing services to other licensees or using a leak test kit supplied by an organization authorized by NRC or an Agreement State to provide leak test kits to other licensees and according to the kit supplier's instructions."

OR

- State: "Leak tests will be performed at intervals approved by NRC or an Agreement State and specified in the Sealed Source and Device Registration Certificate. Leak tests will be performed by an organization authorized by NRC or an Agreement State to provide leak testing services to other licensees or using a leak test kit supplied by an organization authorized by NRC or an Agreement State to provide leak test kits to other licensees and according to the kit supplier's instructions. As an alternative, we will implement the model leak test program published in Appendix L to NUREG-1556, Vol. 17, 'Program-Specific Guidance About Special Nuclear Material of Less Than Critical Mass Licenses,' dated November 2000."

OR

- Provide description of alternative equipment and/or procedures for determining whether there is radioactive leakage from sealed sources.

Note:

- Alternative responses will be reviewed using the criteria listed above.
- If a sealed source is added to an existing license, that license might already authorize the licensee to perform the entire leak test sequence. In this case, the licensee may perform the leak testing on the sealed source according to the procedures previously approved on its license.

References: See the Notice of Availability on the inside front cover of this report to obtain a copy of Draft RG FC 412-4, "Guide for the Preparation of Applications for the Use of Radioactive Materials in Leak-Testing Services," dated June 1985.

8.10.8 SURVEYS

Regulations: 10 CFR 20.1501; 10 CFR 20.2103; 10 CFR 70.56.

Criteria: Licensees are required by 10 CFR 20.1501 to make surveys of potential radiological hazards in their workplace.

Discussion: Surveys are evaluations of radiological conditions and potential hazards (See Figure 8.9). These evaluations may be measurements (e.g., radiation levels measured with survey instrument or results of wipe tests for contamination), calculation, or a combination of measurements and calculations. The selection and proper use of appropriate instruments is one of the most important factors in ensuring that surveys accurately assess the radiological conditions. In order to meet regulatory requirements for surveying, measurements of radiological quantities should be understood in terms of their properties (i.e., alpha, beta, gamma, and neutrons) and compared to the appropriate limits.

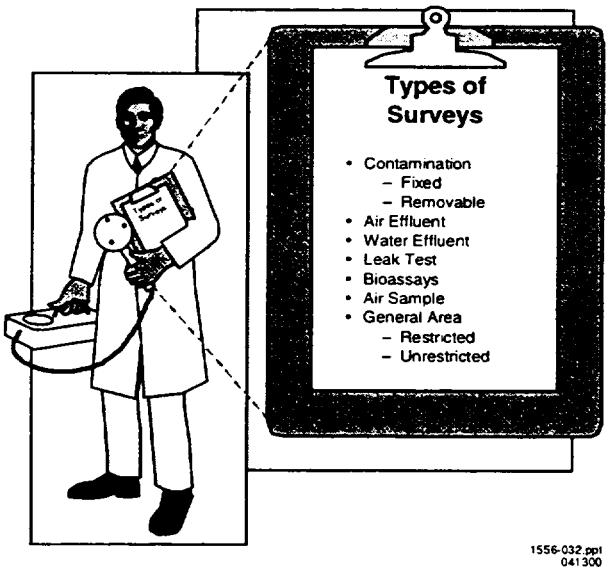


Figure 8.9 Types of Surveys. *There are many different types of surveys performed by Special Nuclear Material licensees.*

Radiation surveys are used to detect and evaluate contamination of:

- Facilities;
- Equipment;
- Personnel (during use, transfer, or disposal of licensed material) (See Figure 8.10);
- Restricted and Unrestricted Areas.

Surveys are also used to plan work in areas where licensed material or radiation exists and to evaluate doses to workers and individual members of the public.

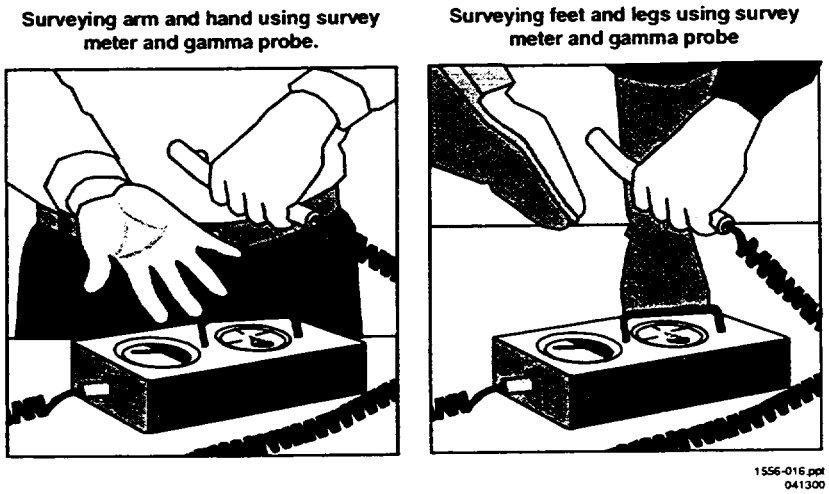


Figure 8.10 Personnel Surveys. *Users of unsealed licensed material should check themselves for contamination (frisk) before leaving the laboratory.*

10 CFR 20.1501 states that surveys are required when it is reasonable under the circumstances to evaluate a radiological hazard and when necessary for the licensee to comply with the regulations. Many different types of surveys may need to be performed due to the particular use of licensed materials. The most important are as follows:

- Surveys for radioactive contamination that could be present on surfaces of floors, walls, laboratory furniture, equipment, and packages of radioactive material received or prepared for shipment;
- Measurements of radioactive material concentrations in air for areas where radioactive materials are handled or processed in unsealed form and where operations could expose workers to the inhalation of radioactive material or where licensed material is or could be released to unrestricted areas;
- Measurements of radioactive material concentrations in water that is released to the environment or to the sanitary sewer;
- Bioassays to determine the kinds, quantities or concentration, and in some cases, the location of radioactive material in the human body; a bioassay can be made by direct measurement (*in vivo* counting) or by analysis and evaluation of material excreted or removed from the human body;
- Surveys of external radiation exposure levels in both restricted and unrestricted areas.

The frequency of routine surveys depends on the nature, quantity, and use of radioactive materials, as well as the specific protective facilities, equipment, and procedures that are designed

to protect the worker from external and internal exposure. Also, the frequency of the survey depends on the type of survey, such as those listed above (see Appendix K).

Not all instruments can measure a given type of radiation. The presence of other radiation may interfere with a detector's ability to measure the radiation of interest. Correct use of radiation detection and measurements is an important aspect of any radiation safety program.

10 CFR Part 20 does not specify limits for surface contamination. Each applicant should propose and justify what removable surface contamination limits will be allowable before decontamination will be performed in each work area. Table K.1 in Appendix K contains contamination limits that are acceptable to NRC.

Response from Applicant: Choose one of the following:

- State: "We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix K to NUREG-1556, Vol. 17, 'Program-Specific Guidance About Special Nuclear Material of Less Than Critical Mass Licenses,' dated November 2000."

OR

- Submit description of alternative equipment and/or procedures to evaluate a radiological hazard.

Note:

Alternative responses will be reviewed using the criteria listed above.

8.10.9 TRANSPORTATION

Regulations: 10 CFR 20.1101; 10 CFR 70.42; 10 CFR 70.51; 10 CFR 71.13; 10 CFR 71.14; 10 CFR 71.18; 10 CFR 71.20; 10 CFR 71.22; 10 CFR 71.24; 10 CFR 71.37; 10 CFR 71.38; 10 CFR 71.47; 10 CFR 71.5; 10 CFR 71.88; Subpart H of 10 CFR Part 71; 49 CFR Parts 171-178.

Criteria: Applicants who will transport or ship licensed material, including radioactive waste, must develop, implement, and maintain safety programs for transport of radioactive material to ensure compliance with NRC and U.S. Department of Transportation (DOT) regulations.

Discussion: Licensees should consider the safety of all individuals who may handle or may come into contact with the packages containing licensed material. Therefore, the primary considerations in packaging licensed material should be to ensure that the package integrity is not compromised during transport, and that the radiation levels (including removable contamination levels) at the package surfaces not only meet the regulatory requirements of 10 CFR 71.47, but are ALARA.

The general licenses in 10 CFR 71.12, 10 CFR 71.18, 10 CFR 71.20, 10 CFR 71.22 and 10 CFR 71.24 provide the authorization used by most Special Nuclear Material of Less than Critical Mass licensees to transport, or offer for transport, packages of radioactive material and specify certain conditions. Most packages offered by Special Nuclear Material of Less than Critical Mass licensees contain quantities of radioactive material that require using a Type A package. However, before offering a Type A package for shipment under the provisions of a general license, the licensee is required to implement an NRC-approved quality assurance (QA) plan. For information about QA plans, see Revision 1 of Regulatory Guide 7.10, "Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material," dated June 1986. For further information about submitting a QA program for review, contact NRC's Spent Fuel Project Office (SFPO) by calling NRC's toll-free number (800) 368-5642, extension 415-8500.

Each licensee must also assure that plutonium in any form, whether for import, export, or domestic shipment, is not transported by air or delivered to a carrier for air transport unless the provisions of 10 CFR 71.88 are fully satisfied.

For additional guidance regarding the transportation of radioactive material, refer to NUREG-1660, "U.S. Specific Schedules of Requirements for Transport of Specified Types of Radioactive Material Consignments." For information about associated fees, contact NRC's Office of the Chief Financial Officer by calling NRC's toll-free number (800) 368-5642, extension 415-7554.

Licensees shipping radioactive waste for disposal must prepare appropriate documentation as specified in 10 CFR 20, Appendix G.

During an inspection, NRC uses the provisions of 10 CFR 71.5 and a Memorandum of Understanding with DOT on the Transportation of Radioactive Material (signed June 6, 1979) to examine and enforce various DOT requirements applicable to Special Nuclear Material of Less than Critical Mass licensees.

Response from Applicant: No response is needed from applicants during the licensing phase. However, before offering a Type A package for shipment under the provisions of a general license, an SNM licensee must obtain NRC's approval of its QA program. Transportation issues will be reviewed during inspection.

References: RAMREG-001-98, "Radioactive Material Regulations Review" can be obtained be calling DOT's Office of Hazardous Material Initiatives and Training at (202) 366-4425.

See the Notice of Availability on the inside front cover of this report to obtain copies of:

- Memorandum of Understanding with DOT on the Transportation of Radioactive Material, signed June 6, 1979;

- Revision 1 of Regulatory Guide 7.10, "Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material," dated June 1986;
- NUREG-1660, "U.S. Specific Schedules of Requirements for Transport of Specified Types of Radioactive Material Consignments."

8.10.10 MINIMIZATION OF CONTAMINATION

Regulations: 10 CFR 20.1406.

Criteria: Applicants must describe how facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste.

Discussion: When designing facilities and developing procedures for their safe use, applicants should think ahead and consider how to minimize radioactive contamination during operation, decontamination and decommissioning efforts, and radioactive waste generation. When submitting new applications, applicants should consider the following:

- Implementation of and adherence to good health physics practices in operations;
- Minimization of areas, to the extent practicable, where licensed materials are used and stored;
- Maximization of the frequency of surveys, within reason, to minimize spread of contamination in the event of a spill;
- Choice of isotope to be used, whenever practical, in consideration of half-life and chemical composition;
- Appropriate filtration of effluent streams;
- Use of non-porous materials for laboratory bench tops, flooring, etc.;
- Ventilation stacks and ductwork with minimal lengths and minimal abrupt changes in direction;
- Use of appropriate plumbing materials with minimal pipelengths and traps;
- Minimization of the number of disposal sites (sinks) where liquid waste is disposed.

SNM Sealed sources and devices that are approved by NRC or an Agreement State and located and used according to their SSD Registration Certificates usually pose little risk of contamination. Leak tests performed as specified in the SSD Registration Certificate should identify defective sources. Leaking sources must be immediately withdrawn from use and decontaminated, repaired, or disposed of according to NRC requirements. These steps minimize the spread of contamination and reduce radioactive waste associated with decontamination efforts. Other efforts to minimize radioactive waste do not apply to programs using only sealed sources and devices that have not leaked.

Response from Applicant: The applicant does not need to provide a response to this item under the following condition. NRC will consider that the above criteria have been met if the applicant's responses meet the criteria in the following sections: Section 8.5.1, "Radioactive Material – Unsealed and/or Sealed Sources," Section 8.9, "Facilities and Equipment," Section 8.10.6, "Radiation Safety Program – Operating and Emergency Procedures," Section 8.10.8, "Radiation Safety Program – Surveys," and Section 8.11, "Radiation Safety Program - Waste Management."

8.11 ITEM 11: WASTE MANAGEMENT

Regulations: 10 CFR 20.1904; 10 CFR 20.2001; 10 CFR 20.2002; 10 CFR 20.2003; 10 CFR 20.2004; 10 CFR 20.2005; 10 CFR 20.2006; 10 CFR 20.2007; 10 CFR 20.2108; 10 CFR 70.51.

Criteria: Radioactive waste must be disposed of in accordance with regulatory requirements and license conditions. Appropriate records of waste disposal must be maintained.

Discussion: Radioactive waste is normally generated when conducting licensed activities. Such waste may include used or unused radioactive material, unusable items contaminated with radioactive material, (e.g., absorbent paper, gloves, etc.). Licensees may not receive radioactive waste from other licensees for processing, storage or disposal, unless specifically authorized to do so by NRC.

All radioactive waste must be stored in appropriate containers until its disposal and the integrity of the waste containers must be assured. Radioactive waste containers must be appropriately labeled. All radioactive waste must be secured against unauthorized access or removal. NRC requires licensees to manage radioactive waste generated at their facilities by one or more of the following methods:

- Transfer to an authorized recipient;
- Release into sanitary sewerage;
- Extended interim storage;
- Obtaining prior approval of NRC of any alternate method;
- Release in effluents to unrestricted areas, other than into sanitary sewerage;
- Incineration.

Licensees may chose any one or more of these methods to dispose of their radioactive waste. It has been NRC's experience that many of the facilities dispose of SNM by the first method. Applicants wanting to dispose of radioactive waste by incineration should contact the appropriate Regional Office of NRC for guidance and refer to Policy and Guidance Directive PG 8-10, "Disposal of Incinerator Ash as Ordinary Waste," dated January 1997. Applicants should note that compliance with NRC regulations does not relieve them of their responsibility to comply with

any other applicable Federal, state, or local regulations. Furthermore, some of the radioactive waste may also include additional hazards, (e.g., biohazard or chemical hazard). Such waste is called "mixed waste," and its storage and disposal must also comply with all other applicable Federal, state, and local regulatory requirements.

Applicants should describe their program for management and disposal of radioactive waste. The program should include procedures for handling of waste, safe and secure storage, characterization, minimization, and disposal of radioactive waste. Appropriate training should be provided to waste handlers. Regulations require that licensees maintain all appropriate records of disposal of radioactive waste. The U.S. Environmental Protection Agency (EPA) issued guidance for developing a comprehensive program to reduce hazardous waste that, in many instances, may also include radioactive waste. NRC transmitted these guidelines to licensees in IN-94-23, "Guidance to Hazardous, Radioactive, and Mixed Waste Minimization Program," dated March 1994.

Release Into Sanitary Sewerage

10 CFR 20.2003 authorizes disposal of radioactive waste by release into a public sanitary sewerage system if each of the following conditions is met:

- Material is readily soluble (or is easily dispersible biological material) in water;
- Quantity of licensed material that the licensee releases into the sewer each month averaged over the monthly volume of water released into the sewer does not exceed the concentration specified in 10 CFR Part 20, Appendix B, Table 3;
- If more than one radioisotope is released, the sum of the ratios of the average monthly discharge of a radioisotope to the corresponding limit in 10 CFR Part 20, Appendix B, Table 3 cannot exceed unity;
- Total quantity of licensed material released into the sanitary sewerage system in a year does not exceed 185 GBq (5 Ci) of H-3, 37 GBq (1 Ci) of C-14, and 37 GBq (1 Ci) of all other radioisotopes (including SNM) combined.

Licensees are responsible to demonstrate that licensed materials discharged into the public sewerage system are indeed readily soluble in water. NRC IN 94-07, "Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage Under the Revised 10 CFR 20," dated January 1994, provides acceptable criteria for evaluating solubility of liquid waste. Liquid scintillation media and ash are examples of material that may or may not be "readily dispersible." Careful consideration should be given to the possibility of reconcentration of radioisotopes that are released into the sewer. NRC alerted licensees to the potentially significant problem of reconcentration of radionuclides released to sanitary sewerage systems in IN 84-94, "Reconcentration of Radionuclides Involving Discharges into Sanitary Sewerage Systems Permitted Under 10 CFR 20.203 (now 10 CFR 20.2003)," dated December 1984.

The regulations in 10 CFR 20.2003 are not applicable for releases to a private sewerage treatment system, a septic system, or leach fields. Licensees may make releases to these systems as effluents released to unrestricted areas pursuant to 10 CFR 20.1301. However, if licensed material is released to a private sewage treatment system, septic system, or leach field, the sludge or other solids from these systems may become contaminated with radioactive material. Such sludge may be required to be disposed of as radioactive waste, using one of the methods described in this section.

Applicants should provide procedures that will ensure that all releases of radioactive waste into the sanitary sewerage meet the criteria stated in 10 CFR 20.2003 and do not exceed the monthly and annual limits specified in regulations. Licensees are required to maintain accurate records of all releases of licensed material into the sanitary sewerage.

Transfer to an Authorized Recipient

Licensees may transfer radioactive waste to an authorized recipient for disposal. It is the licensee's responsibility to verify that the intended recipient is authorized to receive the radioactive waste prior to making any shipment. The waste must be packaged in approved containers for shipment, and each container must identify the radioisotopes and the amounts contained in the waste. Additionally, packages must comply with the requirements of the particular burial site's license and state requirements. Each shipment must comply with all applicable NRC and DOT requirements. In some cases, the waste handling contractor may provide guidance to the licensee for packaging and transportation requirements; however, the licensee is ultimately responsible for ensuring compliance with all applicable regulatory requirements.

The shipper must provide all information required in NRC s Uniform Low-Level Radioactive Waste Manifest, and transfer this recorded manifest information to the intended recipient in accordance with 10 CFR Part 20, Appendix G. Each shipment manifest must include a certification by the waste generator, as specified in Section II of the appendix. Each person involved in the transfer for disposal and disposal of waste, including waste generator, waste collector, waste processor, and disposal facility operator, must comply with requirements specified in Section III of Appendix G.

Licensees should implement procedures to reduce the volume of radioactive waste for final disposal in an authorized low-level radioactive waste (LLW) disposal facility. These procedures include volume reduction by segregating, consolidating, compacting, or allowing certain waste to decay in storage. Waste compaction or other treatments can reduce the volume of radioactive waste, but such processes may pose additional radiological hazards, (e.g., airborne radioactivity) to workers and members of the public. The program should include adequate safety procedures to protect workers, members of the public, and the environment.

Because of the difficulties and costs associated with disposal of sealed sources, applicants should preplan the disposal. Applicants may want to consider contractual arrangements with the source supplier as part of a purchase agreement.

Alternate Methods

Applicants may also request alternate methods for the disposal of radioactive waste generated at their facilities. Such requests must describe the waste containing licensed material, including the physical and chemical properties that may be important to assess risks associated with the waste, and the proposed manner and conditions of waste disposal. Additionally, the applicant must submit its analysis and evaluation of pertinent information on the nature of the environment, nature and location of other affected facilities, and procedures to ensure that radiation doses are maintained ALARA and within regulatory limits.

Some licensees do not have an LLW disposal facility available to them and therefore must use on-site interim storage until such time that a facility becomes available. Licensees should exhaust all possible alternatives for disposal of radioactive waste and rely upon on-site extended interim storage of radioactive waste only as a last resort. The protection of workers and the public is enhanced by disposal rather than storage of waste. Licensees may also find it more economical to dispose of radioactive waste than to store it on-site because as the available capacity decreases, the cost of disposal of radioactive waste may continue to increase. LLW should be stored only when disposal capacity is unavailable and for no longer than is necessary. NRC IN 90-09, "Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licensees," dated February 1990, provides guidance to licensees for requesting an amendment to authorize extended interim storage of LLW.

Response from Applicant:

- Provide a statement that: "We will ensure that all licensed Special Nuclear Material shall be disposed of in accordance with the requirements of 10 CFR Part 20 Subpart K."

OR

- If access to a radioactive waste burial site is unavailable, the applicant should request authorization for extended interim storage of waste. Applicant should refer to NRC IN 90-09, "Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licensees," dated February 1990, for guidance and submit the required information with the application.

Note: Applicants do not need to provide information to NRC if they plan to dispose of LLW via transfer to an authorized recipient.

Alternative responses will be reviewed using the criteria listed above.

References: See the Notice of Availability on the inside front cover of this report to obtain copies of:

- Information Notice 94-23, "Guidance to Hazardous, Radioactive, and Mixed Waste Minimization Program," dated March 1994;
- Information Notice 94-07, "Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage Under the Revised 10 CFR 20," dated January 1994;
- Information Notice 84-94, "Reconcentration of Radionuclides Involving Discharges into Sanitary Sewerage Systems Permitted Under 10 CFR 20.203 (now 10 CFR 20.2003)," dated December 1984;
- Information Notice 90-09, "Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licensees," dated February 1990.

Information Notices are available at <http://www.nrc.gov>.

Additional References:

- Policy and Guidance Directive PG 8-10, "Disposal of Incinerator Ash as Ordinary Waste," dated January 1997.

8.12 ITEM 12: FEES

The next two items on NRC Form 313 are to be completed on the form itself.

On NRC Form 313, enter the appropriate fee category from 10 CFR 170.31 and the amount of the fee enclosed with the application.

8.13 ITEM 13: CERTIFICATION

Individuals acting in a private capacity are required to date and sign NRC Form 313. Otherwise, representatives of the corporation or legal entity filing the application should date and sign NRC Form 313. **Representatives signing an application must be authorized to make binding commitments and to sign official documents on behalf of the applicant.** As discussed previously in Section 3, "Management Responsibility," signing the application acknowledges management's commitment and responsibilities for the radiation protection program. **NRC will return all unsigned applications for proper signature.**

Note:

- It is a criminal offense to make a willful false statement or representation on applications or correspondence (18 U.S.C. 1001).
- When the application references commitments, those items become part of the licensing conditions and regulatory requirements.

9 AMENDMENTS AND RENEWALS TO A LICENSE

It is the licensee's obligation to keep the license current. If any of the information provided in the original application is to be modified or changed, the licensee must submit an application for a license amendment before the change takes place. Also, to continue the license after its expiration date, the licensee must submit an application for a license renewal at least 30 days before the expiration date (10 CFR 2.109, 10 CFR 70.38(a)).

Applications for license amendment, in addition to the following, must provide the appropriate fee. For renewal and amendment requests applicants must do the following:

- Be sure to use the most recent guidance in preparing an amendment or renewal request;
- Submit in duplicate either an NRC Form 313 or a letter requesting amendment or renewal;
- Provide the license number;
- For renewals, provide a complete and up-to-date application if many outdated documents are referenced or there have been significant changes in regulatory requirements, NRC's guidance, the licensee's organization, or radiation protection program. Alternatively, describe clearly the exact nature of the changes, additions, and deletions.

Using the suggested wording of responses and committing to using the model procedures in this report will expedite NRC's review.

10 APPLICATIONS FOR EXEMPTIONS

Regulations: 10 CFR 19.31; 10 CFR 20.2301; 10 CFR 70.11; 10 CFR 71.8.

Criteria: Licensees may request exemptions to regulations. The licensee must demonstrate that the exemption is authorized by law, will not endanger life or property or the common defense and security, and is otherwise in the public interest.

Discussion: Various sections of NRC's regulations address requests for exemptions (e.g., 10 CFR 19.31, 10 CFR 20.2301, 10 CFR 70.11, 10 CFR 71.8). These regulations state that NRC may grant an exemption, acting on its own initiative or on an application from an interested person.

Exemptions are not intended to revise regulations, are not intended for large classes of licenses, and are generally limited to unique situations. Exemption requests must be accompanied by descriptions of the following:

- Exemption and justification why it is needed;
- Proposed compensatory safety measures intended to provide a level of health and safety equivalent to the regulation for which the exemption is being requested;
- Alternative methods for complying with the regulation and why compliance with the existing regulation are not feasible.

Until NRC has granted an exemption in writing, NRC expects strict compliance with all applicable regulations.

11 TERMINATION OF ACTIVITIES

Regulations: 10 CFR 70.25(g); 10 CFR 70.38; 10 CFR 70.51(b).

Criteria: The licensee must do the following:

- Notify NRC, in writing, within 60 days of:
  - — the expiration of its license;
  - — a decision to cease licensed activities permanently at the *entire site* (regardless of contamination levels);
  - — a decision to cease licensed activities permanently in *any separate building or outdoor area*, if they contain residual radioactivity making them unsuitable for release according to NRC requirements;
  - — no principal activities having been conducted *at the entire site* under the license for a period of 24 months;
  - — no principal activities having been conducted for a period of 24 months in *any separate building or outdoor area*, if they contain residual radioactivity making them unsuitable for release according to NRC requirements.
- Submit a decommissioning plan, if required by 10 CFR 70.38(g).
- Conduct decommissioning, as required by 10 CFR 70.38(h) and 10 CFR 70.38(j).
- Submit, to the appropriate NRC Regional Office, completed NRC Form 314, "Certificate of Disposition of Materials" (or equivalent information), and a demonstration that the premises are suitable for release for unrestricted use (e.g., results of final survey).
- Before a license is terminated, send the records important to decommissioning to the appropriate NRC Regional Office. If licensed activities are transferred or assigned in accordance with 10 CFR 70.42, transfer records important to decommissioning to the new licensee.

Discussion: As noted in several instances discussed in "Criteria," before a licensee can decide whether it must notify NRC, the licensee must determine whether residual radioactivity is present and, if so, whether the levels make the building or outdoor area unsuitable for release, according to NRC requirements. A licensee's determination that a facility is not contaminated is subject to verification by NRC inspection.

For guidance on the disposition of licensed material, see Section 8.11, "Waste Management." For guidance on decommissioning records, see Section 8.5.2, "Financial Assurance and Recordkeeping for Decommissioning."

Response from Applicant: The applicant's obligations in this matter begin when the license expires, or at the time the licensee decides to permanently cease principal activities, whichever is earlier. These obligations include undertaking the necessary decommissioning activities,

submitting NRC Form 314 or equivalent information, and performing any other actions as summarized in the Criteria.

Reference: Copies of NRC Form 314, "Certificate of Disposition of Materials," are available upon request from NRC's Regional Offices. (See Figure 2.1 for addresses and telephone numbers).

Appendix A
List of Documents Considered in Development of this NUREG

This report incorporates and updates the guidance previously found in the Regulatory Guides (RG), Policy and Guidance Directives (P&GD), Information Notices (IN), Inspection Procedure (IP), and Technical Assistance Requests (TAR). The guidance incorporated and referenced is listed in Table A.1.

Table A.1 List of Documents Considered in the Preparation of this Report.

Document Identification	Title	Date
ANSI N13.1	Document to Sampling Airborne Radioactive Materials in Nuclear Facilities	1991
ANSI N42.18	Specification and Performance of On-site Instrumentation for Continuously Monitoring Radioactive Effluents	1991
ANSI N323A	Radiation Protection Instrumentation Test and Calibration	1997
Federal Register Notice, Vol. 63, No. 222, p. 64132	Supplemental Information on the Implementation of the Final Rule on Radiological Criteria for License Termination	11/18/98
IN 83-10	Clarification of Several Aspects Relating to Use of NRC-Certified Transport Packages	3/83
IN 84-94	Reconcentration of Radionuclides Involving Discharges into Sanitary Sewerage Systems Permitted Under 10 CFR 20.203 (now 10 CFR 20.2003)	12/84
IN 89-25, Revision 1	Unauthorized Transfer of Ownership or Control of Licensed Activities	12/94
IN 90-09	Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licensees	2/90
IN 94-07	Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage Under the Revised 10 CFR 20	2/94
IN 94-23	Guidance to Hazardous, Radioactive, and Mixed Waste Minimization Program	3/94
IN 96-28	Suggested Guidance Relating to Development and Implementation of Corrective Action	5/96
IN 97-30	Control of Licensed Material During Reorganizations, Employee-Management Disagreements and Financial Crises	6/97

Document Identification	Title	Date
IP 87103	Inspection of Material Licensees Involved in an Incident or Bankruptcy Filing	6/97
IP 87110, Appendix A	Industrial/Academic/Research Inspection Field Notes	2/97
NUREG 1460, Revision 1	Guide to NRC Reporting and Recordkeeping Requirements	7/94
NUREG - 1549	Decision Methods for Dose Assessment to Comply with Radiological Criteria for License Termination	07/98
NUREG - 1600	General Statement of Policy and Procedures on NRC Enforcement Actions	6/95
NUREG-1400	Air Sampling in the Workplace	8/93
NUREG/CR-4884	Interpretation of Bioassay Measurements	7/87
NUREG/CR-5512	Residual Radioactive Contamination From Decommissioning, Parameter Analysis	04/25/96
P&GD FC 83-2, Revision	Renewal of Materials Licenses	8/85
P&GD FC 90-2, Revision 1	Standard Review Plan for Evaluating Compliance with Decommissioning Requirements	4/91
P&GD PG 94-05	Updated Guidance on Decay-In-Storage	10/94
NCRP Report No. 32	Radiation Protection in Educational Institutions	1966
NCRP Report No. 59	Operational Radiation Safety Program	1978
NCRP Report No. 105	Radiation Protection For Medical and Allied Health Personnel	1989
NCRP Report No. 114	Maintaining Radiation Protection Records	1992
Draft RG DG-4006	Demonstrating Compliance with the Radiological Criteria for License Termination	08/98
Draft RG DG-0005	Applications for Licenses of Broad Scope	10/94
Draft RG FC 412-4	Guide for the Preparation of Applications for the Use of Radioactive Materials in Leak-Testing Services	6/85

Document Identification	Title	Date
Draft RG FC 413-4	Guide for the Preparation of Applications for Licenses for the Use of Radioactive Materials in Calibrating Radiation Survey and Monitoring Instruments	6/85
RG 3.66	Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70, and 72	6/90
RG 4.20	Constraints on Release of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors	2/96
RG 8.7, Revision 1	Instructions for Recording and Reporting Occupational Radiation Exposure Data	6/92
RG 8.9	Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program	7/1/93
RG 8.23, Revision 1	Radiation Safety Surveys at Medical Institutions	2/81
RG 3.65	Standard Format and Content of Decommissioning Plans for Licensees Under 10 CFR Part 30, 40, and 70	8/89
RG 8.11	Applications of Bioassay for Uranium	6/94
RG 8.25, Revision 1	Air Sampling in the Workplace	6/92
RG 8.34	Monitoring Criteria and Methods to Calculate Occupational Radiation Doses	7/92
RG 8.37	ALARA Levels for Effluents from Materials Facilities	7/93
RG 8.26	Application of Bioassay for Fission and Activation Products	9/80
SP-96-022	All Agreement States Letter	6/92
	"Air Sampling Instruments," American Conference of Governmental Industrial Hygienists, 7th Edition	1989
	Larson, William A., *A Health Physics Management Program for the Receipt and Shipment of Radioactive Materials*, Proceedings of the Ninth Midyear Topical Symposium of the Health Physics Society on "Operational Health Physics," Denver, CO, USA	1976
	"The Health Physics & Radiological Health Handbook," Revised Edition, Edited by Bernard Shleien	1992

Document Identification	Title	Date
FC 83-3	Standard Review Plan (SRP) For Termination of Special Nuclear Material Licenses of Fuel Cycle Facilities	4/83
FC 83-8, Revision 1	Safeguards Information for Materials Licensees	6/91
FC 83-9	Standard Review Plan (SRP) for Applications to Possess SNM in Quantities Less than a Critical Mass in Any Room or Area	4/83
RAMREG-002	U.S.-Specific Schedules of Requirements for Transport of Specified Types of Radioactive Material Consignments	10/98
	Supplemental Information on the Implementation of the Final Rule on Radiological Criteria for License Termination	11/98

Appendix B
United States Nuclear Regulatory Commission
Form 313

NRC FORM 313 **U. S. NUCLEAR REGULATORY COMMISSION**

(8-1999)
10 CFR 30, 32, 33
34, 35, 36, 39 and 40

APPLICATION FOR MATERIAL LICENSE

APPROVED BY OMB: NO. 3150-0120 EXPIRES:08/31/2002

Estimated burden per response to comply with this mandatory information collection request: 7.4 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the Records Management Branch (T-6 E6), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to bjs1@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO.

LICENSING ASSISTANT SECTION
NUCLEAR MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

SAM NUNN ATLANTA FEDERAL CENTER
U.S. NUCLEAR REGULATORY COMMISSION, REGION II
61 FORSYTH STREET, S.W., SUITE 23T85
ATLANTA, GEORGIA 30303-8931

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
801 WARRENVILLE RD.
LISLE, IL 60532-4351

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-8064

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1 THIS IS AN APPLICATION FOR *(Check appropriate item)*

- ☐ A NEW LICENSE
- ☐ B AMENDMENT TO LICENSE NUMBER _____
- ☐ C RENEWAL OF LICENSE NUMBER _____

2 NAME AND MAILING ADDRESS OF APPLICANT *(Include Zip code)*

3 ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

4 NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

TELEPHONE NUMBER

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5 RADIOACTIVE MATERIAL
a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time

6 PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED

7 INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE

8 TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

9 FACILITIES AND EQUIPMENT

10 RADIATION SAFETY PROGRAM

11 WASTE MANAGEMENT

12 LICENSEE FEES *(See 10 CFR 170 and Section 170.31)*
FEE CATEGORY | AMOUNT ENCLOSED $

13 CERTIFICATION *(Must be completed by applicant)* THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39 AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

CERTIFYING OFFICER – TYPED/PRINTED NAME AND TITLE	SIGNATURE	DATE

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			$		
APPROVED BY				DATE	

Appendix C
Suggested Format for Providing Information Requested in Items 5 Through 11 of NRC Form 313

The table below is designed to help applicants develop their applications. In some instances it is acceptable to simply indicate, by checking the box in the third column (Yes), that applicant commits to adopting the model procedures that are referenced. If the third column contains an asterisk (*), the licensee is expected to describe its program or submit its procedures for the particular item. In this instance, the applicant is requested to check the box in the fourth column indicating that the described program and/or procedures are attached to the application (NRC Form 313). If the third column contains an "N/A," the licensee is not required to describe or submit its programs and/or procedures during the licensing phase. However, these program areas may be reviewed during an inspection.

The table below may also be used as a License Reviewer checklist for applications for SNM licenses.

Table C.1 Suggested Format for Providing Information Requested in Items 5 through 11 of NRC Form 313.

Item No.	Suggested Response	Yes	Description Attached
5.	**RADIOACTIVE MATERIAL** **Unsealed and/or Sealed Sources** • For unsealed materials: – Provide element name with mass number, chemical and/or physical form, and maximum requested possession limit. – For each specified isotope include the principle isotope and significant dose-contributing contaminants. For example the quantity of Pu-236 present in Pu-238 should be specified. • For sealed materials: – Identify each radionuclide(s) (element name and mass number) that will be used in each source. – Provide the manufacturer's (distributor's) name and model number for each sealed source and device requested. – Confirm that each sealed source, device, and source/device combination is registered as an approved sealed source or device by NRC or an Agreement State. – Confirm that the activity per source and maximum activity in each device will not exceed the maximum activity listed on the approved certificate of registration issued by NRC or by an Agreement State. • Provide an Emergency Plan (if required).	*	☐

Item No.	Suggested Response	Yes	Description Attached
	Financial Assurance and Recordkeeping for Decommissioning No response is needed from most applicants. If a certification of financial assurance for decommissioning (F/A) or a decommissioning funding plan (DFP) is required, submit the required documents as described in Regulatory Guide 3.66.	❐	
6.	**PURPOSE FOR WHICH LICENSED MATERIAL WILL BE USED** List the specific use or purpose of each radioisotope.	*	❐
7.	**INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM-RADIATION SAFETY OFFICER (RS0)-TRAINING AND EXPERIENCE** • Provide the name of the proposed RSO. • Describe the proposed RSO's training and experience specific to the licensed material that the applicant intends to use.	*	❐
	• Provide the name of each proposed AU. • Provide information demonstrating that each proposed AU is qualified by training and experience to use the requested licensed materials.	*	❐
8.	**TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS (Occupationally Exposed Individuals and Ancillary Personnel)** Submit a description of the radiation safety training program, including topics covered, groups of workers, assessment of training, qualifications of instructors, and the method and frequency of training and refresher training.	*	❐
9.	**FACILITIES AND EQUIPMENT** Describe the facilities and equipment to be made available at each location where radioactive material will be used. Include a description of the area(s) assigned for the receipt, storage, preparation and measurement of radioactive materials. Submit a diagram showing the locations of shielding, the proximity of radiation sources to unrestricted areas, and other items related to radiation safety. When applicable to facilities where radioactive materials may become airborne, the diagrams should contain schematic descriptions of the ventilation systems, with pertinent airflow rates, pressures, filtration equipment, and monitoring systems. Diagrams should be drawn to a specified scale, or dimensions should be indicated. For facilities where it is anticipated that more than one laboratory or room may be used, a generic laboratory or room diagram may be submitted.	*	❐

Item No.	Suggested Response	Yes	Description Attached
10.	**RADIATION SAFETY PROGRAM** **Audit Program** The applicant is not required to, and should not, submit its audit program to NRC for review during the licensing phase. The adequacy of this audit program will b reviewed during NRC inspection.	Need Not be Submitted with Application	
	Radiation Monitoring Instruments We will use equipment that meets the radiation monitoring instrument specifications and implement the model survey meter calibration program published in Appendix K to NUREG-1556, Vol. 17, 'Program-Specific Guidance About Special Nuclear Material of Less Than Critical Mass Licenses,' dated November 2000.	❒	
	OR We will use equipment that meets the radiation monitoring instrument specifications published in Appendix K to NUREG-1556, Vol. 17, 'Program-Specific Guidance About Special Nuclear Material of Less Than Critical Mass Licenses,' dated November 2000, and instruments will be calibrated by other persons authorized by NRC, an Agreement State, or a licensing State to perform that service.		
	OR A description of alternative minimum equipment to be used for radiation monitoring and/or alternative procedures for the calibration of radiation monitoring equipment.	❒	❒
	Material Receipt and Accountability We have developed, and will implement and maintain, written procedures for safely opening packages that meet the requirements in 10 CFR 20.1906.	*	❒
	AND We will conduct physical inventories of sealed sources of licensed material at intervals not to exceed 6 months.	❒	
	AND We have developed, and will implement and maintain written procedures for licensed material accountability and control to ensure that: • License possession limits are not exceeded; • Licensed material in storage is secured from unauthorized access or removal;	❒	

Item No.	Suggested Response	Yes	Description Attached
	Material Receipt and Accountability (cont'd) • Licensed material not in storage is maintained under constant surveillance and control; and • Records of receipt, transfer, and disposal of licensed material are maintained.		
	Occupational Dose We will maintain, for inspection by NRC, documentation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits in 10 CFR Part 20, or we will monitor individuals in accordance with the criteria in Section 8.10.4, 'Radiation Safety Program – Occupational Dose' in NUREG-1556, Vol. 17, 'Program-Specific Guidance About Special Nuclear Material of Less Than Critical Mass Licenses,' dated November 2000.	Need Not be Submitted with Application	
	Public Dose The applicant's program to control doses received by individual members of the public will be examined during inspection, but should not be submitted in a license application.	Need Not be Submitted with Application	
	Operating and Emergency Procedures Develop and maintain operating procedures for safe use and emergencies. State that such procedures have been developed. In addition, if you want the option to make changes to your operating and emergency procedures, state that procedures may be revised if: • The changes are consistent with the procedures submitted with the license application; • The changes are reviewed and approved by licensee management and the RSO; • Licensee staff is trained in the revised procedures before they are implemented; • The changes do not degrade the effectiveness of the program.	* ❒	❒

Item No.	Suggested Response	Yes	Description Attached
	Leak Test Leak tests will be performed at the intervals approved by NRC or an Agreement State and specified in the SSD Registration Certificate. Leak tests will be performed by an organization authorized by NRC or an Agreement State to provide leak testing services to other licensees or using a leak test kit supplied by an organization authorized by NRC or an Agreement State to provide leak test kits to other licensees and according to the sealed source or plated foil manufacturer's (distributor's) and kit supplier's instructions.	❒	
	OR Leak tests will be performed at the intervals approved by NRC or an Agreement State and specified in the SSD Registration Certificate. Leak tests will be performed by an organization authorized by NRC or an Agreement State to provide leak testing services to other licensees or using a leak test kit supplied by an organization authorized by NRC or an Agreement State to provide leak test kits to other licensees and according to the sealed source or plated foil manufacturer's (distributor's) and kit supplier's instructions. As an alternative, we will implement the model leak test program published in Appendix L to NUREG-1556, Vol. 17, 'Program-Specific Guidance About Special Nuclear Material of Less Than Critical Mass Licenses,' dated November 2000.	❒	
	Survey We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix K to NUREG-1556, Vol. 17, 'Program-Specific Guidance About Special Nuclear Material of Less Than Critical Mass Licenses,' dated November 2000.		
	Transportation The applicant's program for transportation will be examined during inspection, but should not be submitted in a license application.	Need Not Be Submitted with Application	
	Minimization of Contamination The applicant does not need to provide a response to this item under the following condition. NRC will consider that the above criteria have been met if the applicant's responses meet the criteria in: Section 8.5.1, "Radioactive Material – Sealed Sources and Devices or Unsealed Radioactive Material," Section 8.9, "Facilities and Equipment," Section 8.10.6, "Radiation Safety Program – Operating and Emergency Procedures," Section 8.10.8, "Radiation Safety Program – Surveys," and Section 8.11, "Radiation Safety Program – Waste Management."	Need Not Be Submitted with Application	

Item No.	Suggested Response	Yes	Description Attached
11.	**WASTE MANAGEMENT**		
	We will ensure that all licensed Special Nuclear Material shall be disposed of in accordance with the requirements of 10 CFR Part 20 Subpart K.	❒	❒
	OR		
	If access to a radioactive waste burial site is unavailable, the applicant should request authorization for extended interim storage of waste. Applicant should refer to NRC IN 90-09, "Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licensees," dated February 1990, for guidance and submit the required information with the application.	❒	
	Note: Applicants do not need to provide information to NRC if they plan to dispose of LLW via transfer to an authorized recipient.		

Appendix D

Information Needed for Transfer of Control Application

Licensees must provide full information and obtain NRC's *prior written consent* before transferring control of the license; some licensees refer to this as "transferring the license." Provide the following information concerning changes of control by the applicant (transferor and/or transferee, as appropriate). State if any items are not applicable.

1. The new name of the licensed organization. If there is no change, the licensee should so state.
2. The new licensee contact and telephone number(s) to facilitate communications.
3. Any changes in personnel having control over licensed activities, (e.g., officers of a corporation) and any changes in personnel named in the license such as radiation safety officer, authorized users, or any other persons identified in previous license applications as responsible for radiation safety or use of licensed material. The licensee should include information concerning the qualifications, training, and responsibilities of new individuals.
4. Information as to whether the transferor will remain in non-licensed business without the license.
5. A complete, clear description of the transaction, including any transfer of stocks or assets, mergers, etc., so that legal counsel is able, when necessary, to differentiate between name changes and transferring control.
6. A complete description of any planned changes in organization, location, facility, equipment, or procedures (i.e., changes in operating or emergency procedures).
7. A detailed description of any changes in the use, possession, location, or storage of the licensed materials.
8. Any changes in organization, location, facilities, equipment, procedures, or personnel that would require a license amendment even without transferring control.
9. Information as to whether all surveillance items and records (e.g., calibrations, leak tests, surveys, inventories, and accountability requirements) will be current at the time of transfer. Provide a description of the status of all surveillance requirements and records.
10. Confirmation that all records concerning the safe and effective decommissioning of the facility, pursuant to 10 CFR 30.35(g), 40.36(f), 70.25(g), and 72.30(d); public dose; and waste disposal by release to sewers, incineration, radioactive material spills, and on-site burials, have been transferred to the new licensee, if licensed activities will continue at the same location, or to NRC for license terminations.
11. A description of the status of the facility. Specifically, the presence or absence of contamination should be documented. If contamination is present, will decontamination occur before transfer? If not, does the successor company agree to assume full liability for the decontamination of the facility or site?
12. A description of any decontamination plans, including financial assurance arrangements of the transferee, as specified in 10 CFR 30.35, 40.36, and 70.25. Include information about

how the transferee and transferor propose to divide the transferor's assets, and responsibility for any cleanup needed at the time of transfer.

13. Confirmation that the transferee agrees to abide by all commitments and representations previously made to NRC by the transferor. These include, but are not limited to: maintaining decommissioning records required by 10 CFR 30.35(g) and 10 CFR 70.25(g); implementing decontamination activities and decommissioning of the site; and completing corrective actions for open inspection items and enforcement actions.

    With regard to contamination of facilities and equipment, the transferee should confirm, in writing, that it accepts full liability for the site, and should provide evidence of adequate resources to fund decommissioning; or the transferor should provide a commitment to decontaminate the facility before transferring control.

    With regard to open inspection items, etc., the transferee should confirm, in writing, that it accepts full responsibility for open inspection items and/or any resulting enforcement actions; or the transferee proposes alternative measures for meeting the requirements; or the transferor provides a commitment to close out all such actions with NRC before license transfer.

14. Documentation that the transferor and transferee agree to transferring control of the licensed material and activity, and the conditions of transfer; and the transferee is made aware of all open inspection items and its responsibility for possible resulting enforcement actions.

15. A commitment by the transferee to abide by all constraints, conditions, requirements, representations, and commitments identified in the existing license. If not, the transferee must provide a description of its program, to ensure compliance with the license and regulations.

References: The information above is contained in IN-89-25, Revision 1, "Unauthorized Transfer of Ownership or Control of Licensed Activities." See the Notice of Availability on the inside front cover of this report to obtain copies.

Appendix E

Typical Duties and Responsibilities of the Radiation Safety Officer

The RSO's duties and responsibilities include ensuring radiological safety and compliance with NRC and DOT regulations and the conditions of the license see Figure 8.4. Typically, these duties and responsibilities include the following:

- Ensure that licensed material possessed by the licensee is limited to the types and quantities of special nuclear material listed on the license.
- Maintain documentation that demonstrates that the dose to individual members of the public does not exceed the limit specified in 10 CFR 20.1301.
- Ensure security of radioactive material.
- Post documents, as required by 10 CFR Parts 19.11 and 21.6.
- Ensure that licensed material is transported in accordance with applicable NRC and DOT requirements.
- Ensure that radiation exposures are ALARA.
- Oversee all activities involving radioactive material, including monitoring and surveys of all areas in which radioactive material is used.
- Act as liaison with NRC and other regulatory authorities.
- Provide necessary information on all aspects of radiation protection to personnel at all levels of responsibility, pursuant to 10 CFR Parts 19 and 20, and any other applicable regulations.
- Oversee proper delivery, receipt, and conduct of radiation surveys for all shipments of radioactive material arriving at or leaving from the institution, as well as packaging and labeling all radioactive material leaving the institution.
- Determine the need for personnel monitoring, distribute and collect personnel radiation monitoring devices, evaluate bioassays, monitor personnel radiation exposure and bioassay records for trends and high exposures, notify individuals and their supervisors of radiation exposures approaching the limits, and recommend appropriate remedial action.
- Conduct training programs and otherwise instruct personnel in the proper procedures for handling radioactive material prior to use, at periodic intervals (refresher training), and as required by changes in procedures, equipment, regulations, etc.
- Supervise and coordinate the radioactive waste disposal program, including effluent monitoring and recordkeeping on waste storage and disposal records.
- Oversee the storage of radioactive material not in current use, including waste.
- Perform or arrange for leak tests on all sealed sources and calibration of radiation survey instruments.
- Maintain an inventory of all radioisotopes possessed under the license and limit the quantity to the amounts authorized by the license.

- Immediately terminate any unsafe condition or activity that is found to be a threat to public health and safety or property.
- Supervise decontamination and recovery operations.
- Maintain other records not specifically designated above, for example, records of receipts, transfers, and surveys as required by 10 CFR 70.51 and 10 CFR 20, Subpart L, "Records."
- Hold periodic meetings with, and provide reports to, licensee management.
- Ensure that all users are properly trained.
- Perform periodic audits of the radiation safety program to ensure that the licensee is complying with all applicable NRC regulations and the terms and conditions of the license (e.g., leak tests, inventories, use limited to trained, approved users, etc.), the content and implementation of the radiation safety program to achieve occupational doses and doses to members of the public that are ALARA in accordance with 10 CFR 20.1101 and required records are maintained.
- Ensure that the results of audits, identification of deficiencies, and recommendations for change are documented (and maintained for at least 3 years) and provided to management for review; ensure that prompt action is taken to correct deficiencies.
- Ensure that the audit results and corrective actions are communicated to all personnel who use licensed material.
- Ensure that all incidents, accidents, and personnel exposure to radiation in excess of ALARA or Part 20 limits are investigated and reported to NRC and other appropriate authorities, if required, within the required time limits.
- Maintain understanding of and up-to-date copies of NRC regulations, the license, revised licensee procedures, and ensure that the license is amended whenever there are changes in licensed activities, responsible individuals, or information or commitments provided to NRC during the licensing process.

Appendix F

Facilities and Equipment Considerations

Below is a list of topics that should be considered when developing a description of the facilities and equipment that a licensee will use, or otherwise have available. Not every applicant will need to address each topic in their application.

- Restricted areas are defined as areas to which access is limited by the licensee to protect individuals against undue risks from exposure to radiation and radioactive materials. The application should contain detailed descriptions and diagrams of the facilities, including information about the shielding properties of the construction materials used. Scaled drawings and sketches should be submitted showing the relationship between restricted areas and unrestricted areas and the location of all pertinent safety-related equipment.
- Bench top or open work areas may be used for sealed sources, for small quantities of solid materials in a form not likely to become airborne or dispersed, and for small quantities of liquids of such low volatility as not to cause airborne contamination or toxicity problems. Trays and/or absorbent surface covers to catch and retain spilled liquids should be used on these open work surfaces and inside closed systems discussed below. Surfaces should be smooth and non-porous, to facilitate decontamination.
- Radioactive materials that are handled or used in unsealed forms should be confined to control the release of material and to prevent the spread of contamination. Gaseous, volatile, and fine particulate solid materials should be handled in closed or isolated systems such as fume hoods or glove boxes with controlled, and possibly filtered, exhaust systems.

Chemical-type fume hoods provide a working area with controlled inward airflow from the room to the hood exhaust system. Hoods are used for gases, for unsealed volatile licensed materials, and for processes such as evaporation that may release gases and vapors. Fume hoods provide emergency ventilation and exhaust for unplanned releases, such as accidental spills and ruptures, as well as routine exhaust of effluents. Filters may be required in the exhaust stream unless monitoring and/or calculations demonstrate that any planned or likely effluent will be in accordance with the limits found in 10 CFR 20, Appendix B.

Glove boxes are sealed boxes with transparent viewing windows, sealable ports or doors for transferring materials and equipment, and gloves sealed to the box through which licensed materials are handled. Glove boxes are used for the containment during storage and use of liquids and solids that can become airborne particulates or aerosols. Glove boxes can be closed or exhausted, with filtration systems if appropriate, to prevent contamination.

- Sink faucets should be designed, where possible, for operation by foot, knee, or elbow rather than by hand.
- Plumbing and ductwork should be designed to avoid radioactive contamination build-up. This build-up of contamination can create external radiation exposure hazards and problems for decommissioning.
- Shielding consisting of lead or other high-density material in the form of bricks, panels, L-shields, storage containers, or other shapes may be used on bench tops, in fume hoods or in glove boxes to reduce radiation exposure from gamma-emitting radioactive materials.

Similarly, shielding of low atomic number material, such as high-density plastic, may be used to reduce the exposure from high-energy beta-emitting materials. Shielded shipping containers are frequently used for continued storage after receipt of materials.

- A particular sink should be designated for disposal of liquid radioactive waste to the sanitary sewerage system. In some cases, depending on number of users and distance between areas of use, more than one sink may need to be designated.
- Labeled waste containers should be used. These containers may be shielded as necessary, placed near the waste-generating areas and away from areas frequently occupied by personnel. Additionally, these containers should be effectively enclosed to prevent airborne contamination from radioactive materials deposited.
- Remote handling tools, such as forceps or extension handles, should be used to provide distance in the handling of radioactive materials (ALARA). In addition, shielded handling devices, such as shielded syringes, can be used to protect workers from materials that cannot be handled remotely. Pipetting should be done using only appropriate devices. Pipetting by mouth should be strictly forbidden.
- Where appropriate, ventilation systems should be designed such that, in the event of an accident, they can be shut down to prevent the spread of radioactivity.
- Designated areas should be provided for coats and personal belongings, to avoid contamination.
- Areas with background radiation levels should be designated for personnel dosimetry storage when not in use.
- Areas of use should be well-lighted to avoid spills and other accidents that could result in contamination build-up.
- Observation of activities conducted behind shielding with remote tools (or with extended arms and hands, within limits consistent with permissible occupational exposures) can be accomplished by mirrors, through shielded (e.g., leaded glass) windows, through transparent plastic beta shields, or by remote video monitoring.
- The combination of containment, shielding, and handling devices proposed for any use of radioactive materials should be appropriate to the type and quantity of materials to be used and to the type and duration of operations to be conducted.
- If respiratory protective equipment will be used to limit inhalation of airborne licensed material, follow the provisions of 10 CFR Part 20, Subpart H.
- If compaction of waste is performed, ensure that facilities are adequate for the ventilation of the area where the waste is compacted. In addition, also ensure that air sampling for internal exposures is available, if needed per 10 CFR 20.1204.

Appendix G

Suggested Audit Checklist

An audit is conducted, in part, to fulfill the requirements of 10 CFR 20.1101 for an annual review of the content and implementation of the licensee's radiation protection program. It should also identify program weaknesses and allow licensees to take early corrective actions (before an NRC inspection). During an audit, the auditor needs to keep in mind not only the requirements of NRC's regulations, but also the licensee's commitments in its applications and other correspondence with NRC. The auditor should also evaluate whether the licensee is maintaining exposures to workers and the general public as low as is reasonably achievable (ALARA) and, if not, make suggestions for improvement.

The form in this Appendix can be used to document the annual audit of the radiation protection program. Guidance follows on completing each section of the form. In the "remarks" portions of the form, note any deficiencies that were identified and the corrective actions taken (or to be taken).

Section 1, Audit History. Enter the date of the last audit, whether any deficiencies were identified, and whether actions were taken to correct the deficiencies.

Section 2, Organization and Scope of Program. Give a brief description of the organizational structure, noting any changes in personnel. Describe the scope of licensed activities at the audited location. Check whether the Radiation Safety Officer (RSO) is the person identified in the license and fulfills the duties specified in the license. Ensure use by authorized individuals.

Section 3, Training, Retraining, and Instructions to Workers. Ensure that workers have received the training required by 10 CFR 19.12. Be sure that, before being permitted to use licensed material, the user has received training and has a copy of the licensee's safe use and emergency procedures. Note whether refresher training is conducted in accordance with licensee commitments. By interview and/or observation of selected workers, ensure that each has a copy of the licensee's procedures and can implement them properly.

Section 4, Audits. Verify that audits fulfill the requirements of 10 CFR 20.1101, are conducted in accordance with licensee commitments, and are properly documented.

Section 5, Facilities. Verify that the licensee's facilities are as described in its license documents.

Section 6, Materials. Verify that the license authorizes the quantities and types of material that the licensee possesses.

Section 7, Leak Tests. Verify that all sealed/plated foil sources are tested for leakage at the prescribed frequency and in accordance with licensee commitments. Records of results should be maintained.

Section 8, Inventories. Verify that inventories are conducted at least once every 6 months to account for all sources; inventory records should be maintained.

Section 9, Radiation Surveys. Verify that the licensee has appropriate, operable and calibrated survey instruments available, that the instruments are calibrated (at the required frequency) in accordance with license conditions and in accordance with 10 CFR 20.2103. Calibration records must be retained for 3 years after the record is made. Check that radiation levels in areas adjacent to use are within regulatory limits and in accordance with 10 CFR 20.2103. Verify compliance with 10 CFR 20.1301. Records of surveys must be retained for 3 years after the record is made.

Section 10, Receipt and Transfer of Radioactive Material (Includes Waste Disposal). Verify that packages containing licensed material, received from others, are received, opened, and surveyed in accordance with 10 CFR 20.1906. Ensure that transfers are performed in accordance with 10 CFR 70.42 and 10 CFR 70.54. Records of surveys, receipt, and transfer must be maintained in accordance with 10 CFR 20.2103, 10 CFR 70.51(b)(5).

Section 11, Transportation. Determine compliance with Department of Transportation (DOT) requirements. Verify that radioactive packages are prepared, marked, and labeled in accordance with 49 CFR Parts 172 and 173 requirements. Verify that shipping papers are prepared, that they contain all needed information, and that they are readily accessible during transport (49 CFR 172.200, 201, 202, 203, 204 and 177.718).

Section 12, Personnel Radiation Protection. Evaluate the licensee's determination that unmonitored personnel are not likely to receive more than 10 % of the allowable limits. Alternately, if personnel dosimetry is provided and required, verify that it complies with 10 CFR 20.1501(c) and licensee commitments. Review personnel monitoring records; compare exposures of individuals doing similar work; determine reasons for significant differences in exposures. If any worker declared her pregnancy in writing, evaluate the licensee's compliance with 10 CFR 20.1208. Check whether records are maintained as required by 10 CFR 20.2101, 20.2102, 20.2103, 20.2104 and 20.2106.

Section 13, Auditor's Independent Measurements (If Made). The auditor should make independent survey measurements and compare the results with those made or used by the licensee.

Section 14, Notification and Reports. Check on the licensee's compliance with the notification and reporting requirements in 10 CFR Parts 19, 20, and 70. Ensure that the licensee is aware of the telephone number for NRC's Emergency Operations Center; (301) 816-5100.

Section 15, Posting and Labeling. Check for compliance with the posting and labeling requirements of 10 CFR 19.11, 20.1902, 20.1904, and 21.6.

Section 16, Recordkeeping for Decommissioning. Check to determine compliance with 10 CFR 70.25(g).

Section 17, Bulletins and Information Notices. Check to determine if the licensee is receiving bulletins, information notices, NMSS Newsletters, etc., from NRC. Check whether the licensee took appropriate action in response to NRC mailings.

Section 18, Special License Conditions or Issues. Verify compliance with any special conditions on the licensee's license. If the licensee has any unusual aspect of its work, review and evaluate compliance with regulatory requirements.

Section 19, Continuation of Report Items. This section is self-explanatory.

Section 20, Problems or Deficiencies Noted; Recommendations. This section is self-explanatory.

Section 21, Evaluation of Other Factors. Evaluate licensee management's involvement with the radiation safety program, whether the RSO has sufficient time to perform his/her duties, and whether the licensee has sufficient staff to handle the workload and maintain compliance with regulatory requirements.

Note: All areas indicated in audit notes may not be applicable to every license and may not need to be addressed during each audit.

Sample Checklist

Audit Report No. _____ License No. _____

Licensee's name and mailing address:

_____

_____

_____

_____

Audit of activities at (Address):

_____

_____

_____

_____

Contact at Audit Location _____ Telephone No. _____

Date of this Audit _____

Summary of Findings and Action:

❒ No deficiencies

❒ Deficiencies

❒ Action on previous deficiencies

Recommendations:

Auditor _____ Date _____

(Signature)

1. AUDIT HISTORY ❒ N/A (N/A means "Not applicable" – Initial Audit)

A. Last audit of this location conducted _____

B. Problems/deficiencies identified during last two audits or two years, whichever is longer

❒ Y ❒ N

C. Open problems/deficiencies from previous audits:

Status Requirement	Prob./Def.	Corrective Action Taken (Y/N)	Open/Closed

D. Any previous problem/deficiency not corrected or repeated ❒ Yes ❒ No ❒ N/A

Explain:

2. ORGANIZATION AND SCOPE OF PROGRAM

A. Briefly describe organizational structure and note any personnel changes.

1. Structure is as described in license documents? ❒ Yes ❒ No
2. Multiple authorized locations of use? ❒ Yes ❒ No
3. Briefly describe scope of activities involving licensed material, frequency of use, staff size, etc.

B. Radiation Safety Officer ❒ Yes ❒ No

1. Authorized on license ❒ Yes ❒ No
2. Fulfills duties as RSO ❒ Yes ❒ No

C. Use only by authorized individuals ❒ Yes ❒ No

Remarks:

3. TRAINING, RETRAINING, AND INSTRUCTIONS TO WORKERS

A. Instructions to workers per [10 CFR 19.10] ☐ Yes ☐ No

B. Training program required ☐ Yes ☐ No

C. Training records maintained ☐ Yes ☐ No

D. Evaluation of individuals' understanding of procedures and regulations based on interviews, observation of selected workers ☐ Yes ☐ No

1. Each has an up-to-date copy of the licensee's safe use and emergency procedures ☐ Yes ☐ No

2. Adequate understanding of:

a. Current safe use procedures ☐ Yes ☐ No

b. Emergency procedures ☐ Yes ☐ No

E. Revised Part 20, Workers cognizant of requirements for:

1. Radiation Safety Program [20.1101] ☐ Yes ☐ No

2. Annual dose limits [20.1301, 20.1302] ☐ Yes ☐ No

3. New NRC Forms 4 and 5 ☐ Yes ☐ No

4. 10% monitoring threshold [20.1502] ☐ Yes ☐ No

5. Dose limits to embryo/fetus and declared pregnant women [20.1208] ☐ Yes ☐ No

6. Procedures for opening packages [20.1906] ☐ Yes ☐ No

Remarks:

4. INTERNAL AUDITS, REVIEWS OR INSPECTIONS

A. Audits are conducted ☐ Yes ☐ No

1. Audits conducted by _____

2. Frequency _____

B. Content and implementation of the radiation protection program reviewed annually [20.1101(c)] ☐ Yes ☐ No

C. Records maintained [20.2102] ☐ Yes ☐ No

5. FACILITIES

Facilities as described in license application ❒ Yes ❒ No

Remarks:

6. MATERIALS

Isotopes, quantities, and use as authorized on license ❒ Yes ❒ No

Remarks:

7. LEAK TESTS

A. Leak test performed as described in correspondence with NRC (consultant; leak test kit; licensee performed) ❒ Yes ❒ No

B. Frequency: every 6 months or other interval, as approved by NRC or Agreement State ❒ Yes ❒ No

C. Records with appropriate information maintained ❒ Yes ❒ No

Remarks:

8. INVENTORIES

A. Conducted at 6-month intervals ❒ Yes ❒ No

B. Records with appropriate information maintained ❒ Yes ❒ No

Remarks:

9. RADIATION SURVEYS

A. Instruments and Equipment: ❒ Yes ❒ No

1. Appropriate operable survey instrumentation possessed or readily available ❒ Yes ❒ No
2. Calibrated as required [20.1501] ❒ Yes ❒ No
3. Calibration records maintained [20.2103(a)] ❒ Yes ❒ No

B. Briefly describe survey requirements [20.1501(a)]:

C. Performed as required [20.1501(a)] ❒ Yes ❒ No

1. Radiation levels within regulatory limits ❒ Yes ❒ No
2. Corrective action taken and documented ❒ Yes ❒ No

D. Records maintained [20.2103] ❒ Yes ❒ No

E. Protection of members of the public

1. Adequate surveys made to demonstrate either (a) that the TEDE to the individual likely to receive the highest dose does not exceed 100 mrem in a year, or (b) that if an individual were continuously present in an unrestricted area, the external dose would not exceed 2 mrem in any hour and 50 mrem in a year [20.1301(a)(1), 1302(b)] ❒ Yes ❒ No
2. Unrestricted area radiation levels do not exceed 2 mrem in any one hour [20.1301(a)(2)] ❒ Yes ❒ No
3. Records maintained [20.2103, 2107] ❒ Yes ❒ No

Remarks:

10. RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL (INCLUDES WASTE DISPOSAL)

A. Describe how packages are received and by whom:

B Written package opening procedures established and followed [20.1906(e)] ❒ Yes ❒ No

C. If package shows evidence of degradation, monitor for contamination and radiation levels ❒ Yes ❒ No ❒ N/A

D. Monitoring of degraded packages performed within time specified [20.1906(c)] ❒ Yes ❒ No ❒ N/A

E. Transfer(s) between licensees (including "disposal") performed per 70.36 and 70.42 ❒ Yes ❒ No ❒ N/A

F. Records of receipt/transfer maintained [20.2103(a), 70.51(b)(1)] ❒ Yes ❒ No

G. Transfers within licensee's authorized users or locations performed as required [L/C] ❒ Yes ❒ No ❒ N/A

H. Package receipt/distribution activities evaluated for compliance with 20.1301 [20.1302] ❒ Yes ❒ No ❒ N/A

Remarks:

11. TRANSPORTATION (10 CFR 71.5(a) and 49 CFR 170-189) ❒ N/A

A. Licensee shipments are:

1. Delivered to common carriers ❒ Yes ❒ No ❒ N/A
2. Transported in licensee's own private vehicle ❒ Yes ❒ No ❒ N/A
3. No shipments since last audit ❒ Yes ❒ No ❒ N/A

B. Packages ❒ N/A

1. Authorized packages used [173.415, 416(b)] ❒ Yes ❒ No ❒ N/A
2. Closed and sealed during transport [173.475(f)] ❒ Yes ❒ No

C. Shipping Papers ❒ N/A

1. Prepared and used [172.200(a)] ❒ Yes ❒ No
2. Proper {Shipping name, Hazard Class, UN Number, Quantity, Package Type, Nuclide, RQ, Radioactive Material, Physical and Chemical Form, Activity, Category of label, TI, Shipper's Name, Certification and Signature, Emergency Response Phone Number, "Cargo Aircraft Only" (if applicable)} [172.200-204] ❒ Yes ❒ No
3. Readily accessible during transport [177.718(e)] ❒ Yes ❒ No

D. Vehicles ❒ Yes ❒ No

1. Cargo blocked and braced [177.842(d)] ❒ Yes ❒ No
2. Placarded, if needed [172.504] ❒ Yes ❒ No
3. Proper overpacks, if used (shipping name, UN Number, labeled, statement indicating that inner package complies with specification package) [173.25] ❒ Yes ❒ No

E. Any incidents reported to DOT [171.15, 16] ❒ Yes ❒ No

Remarks:

12. PERSONNEL RADIATION PROTECTION

A. ALARA considerations are incorporated into the Radiation Protection Program [20.1101(b)] ☐ Yes ☐ No

B. Adequate documentation of determination that unmonitored occupationally individuals are not likely to receive >10% of allowable limit [20.1502(a)] ☐ Yes ☐ No ☐ N/A

OR

C. External dosimetry provided and required ☐ Yes ☐ No ☐ N/A

1. Supplier _____ Frequency _____
2. Supplier is NVLAP-approved [20.1501(c)] ☐ Yes ☐ No
3. Dosimeters exchanged at required frequency [L/C]] ☐ Yes ☐ No

D. Occupational intake monitored and assessed [20.1502(b)] ☐ Yes ☐ No ☐ N/A

E. Reports ☐ N/A

1. Reviewed by _____ Frequency _____
2. Auditor reviewed personnel monitoring records for period _____ to _____
3. Prior dose determined for individuals likely to receive doses [20.2104] ☐ Yes ☐ No
4. Maximum exposures TEDE _____ Other_____
5. NRC Forms or equivalent [20.2104(d), 2106(c)]
   a. NRC Form 4 "Cumulative Occupational Exposure History" ☐ Yes ☐ No

      Complete: ☐ Yes ☐ No

   b. NRC Form 5 "Occupational Exposure Record for a Monitoring Period" ☐ Yes ☐ No

      Complete: ☐ Yes ☐ No
6. Worker declared her pregnancy in writing during inspection period (review records) ☐ Yes ☐ No ☐ N/A

   If yes, determine compliance with [20.1208] ☐ Yes ☐ No

   Check for records per [20.2106(e)] ☐ Yes ☐ No

F. Records of exposures, surveys, monitoring, and evaluations maintained [20.2102, 2103, 2106, L/C] ☐ Yes ☐ No

Remarks:

13. AUDITOR'S INDEPENDENT MEASUREMENTS (IF MADE)

A. Survey instrument Serial No. Last calibration

_____

_____

B. Auditor's measurements compared to licensee's ❒ Yes ❒ No

C. Describe the type, location, and results of measurements:

14. NOTIFICATION AND REPORTS ❒ N/A

A. Licensee in compliance with [19.13, 70.50] (reports to individuals, public and occupational, monitored to show compliance with Part 20) ❒ Yes ❒ No ❒ N/A

B. Licensee in compliance with [20.2201, 70.50] (theft or loss) ❒ Yes ❒ No ❒ None

C. Licensee in compliance with [20.2202, 70.50] (incidents) ❒ Yes ❒ No ❒ None

D. Licensee in compliance with [20.2203, 70.50] (overexposures and high radiation levels) ❒ Yes ❒ No ❒ None

E. Licensee aware of telephone number for NRC Emergency Operations Center [(301) 816-5100] ❒ Yes ❒ No

15. POSTING AND LABELING

A. NRC Form 3 "Notice to Workers" is posted [19.11] ❒ Yes ❒ No

B. Parts 19, 20, 21, Section 206 of Energy Reorganization Act, procedures adopted pursuant to Part 21, and license documents are posted, or a notice indicating where documents can be examined is posted [19.11, 21.6] ❒ Yes ❒ No

C. Other posting and labeling per [20.1902, 1904] and the license is not exempted by [20.1903, 1905] ❒ Yes ❒ No

Remarks:

16. RECORDKEEPING FOR DECOMMISSIONING

A. Records of information important to the safe and effective decommissioning of the facility maintained in an independent and identifiable location until license termination ☐ Yes ☐ No

B. Records include all information outlined in [70.25(g)] ☐ Yes ☐ No

Remarks:

17. BULLETINS AND INFORMATION NOTICES

A. Receipt of NRC Bulletins, NRC Information Notices, NMSS newsletters, etc. ☐ Yes ☐ No

B. Appropriate action taken in response to Bulletins, Information notices, etc. ☐ Yes ☐ No

Remarks:

18. SPECIAL LICENSE CONDITIONS OR ISSUES ☐ N/A

A. Review special issue conditions or other issues, and describe findings:

B. Problems/deficiencies identified at licensee facilities other than at audit location:

C. Evaluation of compliance:

19. CONTINUATION OF REPORT ITEMS ☐ N/A

(If more space is needed, use separate sheets and attach to report.)

20. PROBLEMS OR DEFICIENCIES NOTED; RECOMMENDATIONS ☐ N/A

Note: Briefly state (1) the requirement and (2) how and when violated. Provide recommendations for improvement.

21. EVALUATION OF OTHER FACTORS

A. Senior licensee management is appropriately involved with the radiation safety program and/or RSO oversight ☐ Yes ☐ No

B. RSO has sufficient time to perform his/her radiation safety duties and is not too busy with other assignments ☐ Yes ☐ No

C. Licensee has sufficient staff ☐ Yes ☐ No

Remarks/recommendations:

Appendix H

Radiation Monitoring, Instrument Specifications, and Model Survey Instrument Calibration Program

The specifications in Table H.1 will help applicants and licensees choose the proper radiation detection equipment for monitoring the radiological conditions at their facility(ies).

Table H.1 Typical Survey Instruments[1]. (Instruments used to measure radiological conditions at licensed facilities.)

Portable Instruments Used for Contamination and Ambient Radiation Surveys			
Detectors	**Radiation**	**Energy Range**	**Efficiency**
Exposure Rate Meters	Gamma, X-ray	μR-R	N/A
Count Rate Meters			
GM	Alpha	All energies (dependent on window thickness)	Moderate
	Beta	All energies (dependent on window thickness)	Moderate
Neutron	Neutron		
	Gamma	All energies	< 1%
NaI Scintillator	Gamma	All energies (dependent on crystal thickness)	Moderate
ZnS	Alpha	All energies	Moderate
Plastic Scintillator	Beta	C-14 or higher (dependent on window thickness)	Moderate
Stationary Instruments Used to Measure Wipe, Bioassay, and Effluent Samples			
Detectors	**Radiation**	**Energy Range**	**Efficiency**
Liquid Scintillation Counting*	Alpha	All energies	High
	Beta	All energies	High
	Gamma		Moderate
Gamma Counter (NaI)*	Gamma	All energies	High
Gas Proportional	Alpha	All energies	High
	Beta	All energies	Moderate
	Gamma	All energies	< 1%

[1] Table from The Health Physics & Radiological Health Handbook, Revised Edition, Edited by Bernard Shleien, 1992 (except for * items).

Model Instrument Calibration Program

Training

Before allowing an individual to perform survey instrument calibrations, the RSO will ensure that he or she has sufficient training and experience to perform independent survey instrument calibrations.

Classroom training may be in the form of lecture, videotape, or self-study and should cover the following subject areas:

- Principles and practices of radiation protection;
- Radioactivity measurements, monitoring techniques, and using instruments;
- Mathematics and calculations basic to using and measuring radioactivity;
- Biological effects of radiation.

Appropriate on-the-job-training consists of the following:

- Observing authorized personnel performing survey instrument calibration;
- Conducting survey meter calibrations under the supervision and in the physical presence of an individual authorized to perform calibrations.

Facilities and Equipment for Calibration of Dose Rate or Exposure Rate Instruments

- To reduce doses received by individuals not calibrating instruments, calibrations should be conducted in an isolated area of the facility or at times when no one else is present.
- Individuals conducting calibrations should wear assigned dosimetry.
- Individuals conducting calibrations should use a calibrated and operable survey instrument to ensure that unexpected changes in exposure rates are identified and corrected.

Model Procedure for Calibrating Survey Instruments

A radioactive sealed source(s) used for calibrating survey instruments will:

- Approximate a point source;
- Have its apparent source activity or the exposure rate at a given distance traceable by documented measurements to a standard certified by National Institutes of Standards and Technology (NIST);

- Approximate the same energy and type of radiation as the environment in which the calibrated device will be employed;
- For dose rate and exposure rate instruments, the source should be strong enough to give an exposure rate of at least about 7.7 x 10^{-6} coulombs/kilogram/hour (30 mR/hr) at 100 cm (e.g., 3.1 gigabecquerels (85 mCi) of cesium-137 or 7.8 x 102 megabecquerels (21 mCi) of cobalt-60).

The three kinds of scales frequently used on dose or dose rate survey meters are calibrated as follows:

- Linear readout instruments with a single calibration control for all scales shall be adjusted at the point recommended by the manufacturer or at a point within the normal range of use. Instruments with calibration controls for each scale shall be adjusted on each scale. After adjustment, the response of the instrument shall be checked at approximately 20% and 80% of full scale. The instrument's readings shall be within ± 15% of the conventionally true values for the lower point and ± 10% for the upper point.
- Logarithmic readout instruments, which commonly have a single readout scale spanning several decades, normally have two or more adjustments. The instrument shall be adjusted for each scale according to site specifications or the manufacturer's specifications. After adjustment, calibration shall be checked at a minimum of one point on each decade. Instrument readings shall have a maximum deviation from the conventionally true value of no more than 10% of the full decade value.
- Meters with a digital display device shall be calibrated the same as meters with a linear scale.
- Readings above 2.58 X 10^{-4} coulomb/kilogram/hour (1 R/hr) need not be calibrated, but such scales should be checked for operation and response to radiation.
- The inverse square and radioactive decay law should be used to correct changes in exposure rate due to changes in distance or source decay.

Surface Contamination Measurement Instruments

- Survey meters' efficiency must be determined by using radiation sources with similar energies and types of radiation that the survey instrument will be used to measure.
- If each scale has a calibration potentiometer, the reading shall be adjusted to read the conventionally true value at approximately 80% of full scale, and the reading at approximately 20% of full scale shall be observed. If only one calibration potentiometer is available, the reading shall be adjusted at mid-scale on one of the scales, and readings on the other scales shall be observed. Readings shall be within 20% of the conventionally true value.

Model Procedures for Calibrating, Liquid Scintillation Counters, Gamma Counters, Gas Flow Proportional Counters, and Multichannel Analyzers

A radioactive sealed source used for calibrating instruments will do the following:

- Approximate the geometry of the samples to be analyzed;
- Have its apparent source activity traceable by documented measurements to a standard certified by National Institutes of Standards and Technology (NIST);
- Approximate the same energy and type of radiation as the samples that the calibrated device will be used to measure.

Calibration

- Calibration must produce readings within ± 20 per cent of the actual values over the range of the instrument.
- Calibration of liquid scintillation counters will include quench correction.

Calibration Records

Calibration records, for all survey instruments, should indicate the procedure used and the data obtained. The description of the calibration should include:

- The owner or user of the instrument;
- A description of the instrument, including the manufacturer's name, model number, serial number, and type of detector;
- A description of the calibration source, including the exposure rate at a specified distance or activity on a specified date;
- For each calibration point, the calculated exposure rate or count rate, the indicated exposure rate or count rate, the deduced correction factor (the calculated exposure rate or count rate divided by the indicated exposure rate or count rate), and the scale selected on the instrument;
- For instruments with external detectors, the angle between the radiation flux field and the detector (i.e., parallel or perpendicular);
- For instruments with internal detectors, the angle between radiation flux field and a specified surface of the instrument;
- For detectors with removable shielding, an indication whether the shielding was in place or removed during the calibration procedure;
- The exposure rate or count rate from a check source, if used;
- The name of the person who performed the calibration and the date it was performed.

The following information should be attached to the instrument as a calibration sticker or tag:

- For exposure rate meters, the source isotope used to calibrate the instrument (with correction factors) for each scale;
- The efficiency of the instrument, for each isotope the instrument will be used to measure (if efficiency is not calculated before each use);
- For each scale or decade not calibrated, an indication that the scale or decade was checked only for function but not calibrated;
- The date of calibration and the next calibration due date;
- The apparent exposure rate or count rate from the check source, if used.

Air Sampler Calibration

In order to assess accurately the air concentration of radioactive materials in a given location, the volume of air sampled and the quantity of contaminant in the sample must be determined. Accurate determination of the volume of air sampled requires standard, reproducible, and periodic calibration of the air metering devices that are used with air sampling instruments.

The publication entitled "Air Sampling Instruments" found in the 7th Edition, American Conference of Governmental Industrial Hygienists, 1989, provides guidance on total air sample volume calibration methods acceptable to NRC staff, as supplemented below.

Frequency of Calibration

- A licensee committed to a routine or emergency air sampling program should perform an acceptable calibration of all airflow or volume metering devices at least annually (See Regulatory Guide 8.25).
- Special calibrations should be performed at any time there is reason to believe that the operating characteristics of a metering device have been changed, by repair or alteration, or whenever system performance is observed to have changed significantly.
- Routine instrument maintenance should be performed as recommended by the manufacturer.
- Primary or secondary standard instruments used to calibrate air sampling instruments should be inspected frequently for consistency of performance.

Error Limit For Measurement of Air Sample Volume

Most methods of calibrating airflow or air volume metering devices require direct comparison to a primary or secondary standard instrument, to determine a calibration curve or a correction factor. An example of a primary standard is a spirometer that measures total air volume directly with high precision by liquid displacement. An example of a secondary standard is a wet-test meter that has

been calibrated against a primary standard. Primary standards are usually accurate to within ± 1% and secondary standards to within ± 2%.

The following are significant errors associated with determining the total air volume sampled:

E_C: The error in determining the calibration factor. (An acceptable estimate is the percentage error associated with the standard instrument used in the calibration.)[2]

E_S: Intrinsic error in reading the meter scale. (An acceptable estimate is the percentage equivalent of one-half of the smallest scale division, compared to the scale reading.)

E_t: The percentage error in measurement of sampling time that should be kept within 1%.

E_V: The most probable value of the cumulative percentage error in the determination of the total air volume sampled.

E_V: Can be calculated from the following equation, provided there are no additional significant sources of errors:

$$E_V = [E_S^2 + E_C^2 + E_t^2]^{1/2}$$

The most probable value of the cumulative error EV, in the determination of total volume, should be less than 20%.

A sample calculation of the most probable value of the cumulative error in total volume measured is as follows: If accuracies of the scale reading, the calibration factor, and sample time are ± 4, 2, and 1 per cent, respectively, and there are no other significant sources of error, the cumulative error would be:

$$E_V = [4^2 + 2^2 + 1^2]^{1/2} = 4.58\% \text{ or approx. } 5\%$$

If there are significant differences in pressure and temperature between the calibration site and the sampling site, appropriate corrections should be made using the ideal gas laws provided below:

$$Vs = V1 * (P1/760) * (273/T1)$$

[2] The calibration factor should be based on two kinds of determinations. First, correction factors should be determined at several flow rates distributed over the full-scale range. Each flow rate correction factor should be determined while adjusting flow rates upscale and again while adjusting flow rates downscale, and the two sets of data should be compared. Second, subsequent calibrations should compare the new correction factors to those determined during the previous calibration. If observed differences are significant compared to the overall volume error limit of 20 per cent, an additional error term should be included in the calculation above.

where Vs = volume at standard conditions (760 mm & 0C)

V1 = volume measured at conditions P1 and T1

T1 = temperature of V1 in K

P1 = pressure of V1 in mm Hg

Documentation of Calibration of Air Metering Devices

The licensee should maintain records of all routine and special calibrations of airflow or volume metering devices, including the primary or secondary standard used, method employed, and estimates of accuracy of the calibrated metering devices. All instruments should be clearly labeled as to the date and results of the most recent calibration and should include the appropriate correction factors to be used.

References: See the Notice of Availability on the inside front cover of this report to obtain a copy of:

- Draft Regulatory Guide FC 413-4, "Guide for the Preparation of Applications for Licenses for the Use of Radioactive Materials in Calibrating Radiation Survey and Monitoring Instruments," dated June 1985;
- Regulatory Guide 8.25, Revision 1, "Air Sampling in the Workplace," dated June 1992;
- NUREG-1400, "Air Sampling in the Workplace," dated September 1993.

Additional References:

- The Health Physics & Radiological Health Handbook, Revised Edition, Edited by Bernard Shleien, dated 1992.
- ANSI N323A-1997, "Radiation Protection Instrumentation Test and Calibration." Copies may be obtained from the American National Standards Institute, 1430 Broadway, New York, NY 10018 or ordered electronically at the following address: <http://www.ansi.org>.
- "Air Sampling Instruments," American Conference of Governmental Industrial Hygienists, 7th Edition, dated 1989.

Appendix I

Guidance for Demonstrating that Unmonitored Individuals are Not Likely to Exceed 10 Percent of the Allowable Limits

Dosimetry is required for individuals likely to receive, in 1 year from sources external to the body, a dose in excess of 10% of the applicable regulatory limits in 10 CFR 20.1201. To demonstrate that dosimetry is *not* required, a licensee needs to perform a prospective evaluation to demonstrate that its workers are not likely to exceed 10% of the applicable annual limits.

The most common way that individuals might exceed 10% of the applicable limits is by being involved in the processing of sealed sources and/or unsealed material, (e.g., assembly lines, manufacturing processes and quality control activities). This could include internal radioactive uptake, as well as external radiation exposure. However, for many processes, even these activities result in the individual receiving minimal doses. Before allowing workers to perform these tasks, a licensee will need to evaluate the doses that its workers might receive to assess whether dosimetry is required. This is known as a prospective evaluation.

Example

One university has estimated the doses to the extremities and whole body of a person conducting foil activation experiments using Pu-238/Beryllium (Be) sources. Each Pu-238/Be source is authorized to contain up to 352 grams of plutonium. The university based its estimate on observations of individuals performing the recommended procedure according to accepted radiation safety practices. The university had the following types of information:

- Time needed to perform the entire procedure (e.g., 15 minutes);
- Expected dose rate received by the whole body of the individual, associated with the shielded source and determined using measured or manufacturer-determined data (e.g., 0.02 mSv/hr [2 mrem/hr] at 46 cm [18.1 in] from the shield);
- Time the hands were exposed to the shielded source (e.g., 6 min);
- Expected dose rate received by the extremities of the individual, associated with the shielded source and determined using measured or manufacturer-determined data on contact with the shield (e.g., 0.15 mSv/hr [15 mrem/hr]).

From this information, the university estimated that the individual performing each foil activation experiment could receive the following:

- Less than 0.005 mSv [0.5 mrem] TEDE (whole body); and
- 0.015 mSv [1.5 mrem] to the hands.

The applicable TEDE (whole body) limit is 50 mSv (5 rem) per year and 10% of that value is 5 mSv (500 millirem) per year. If one of these procedures delivers 0.005 mSv (0.5 mrem), then an individual could perform 1,000 of these experiments each year and remain within 10% of the applicable limit.

The applicable SDE (extremities) is 500 mSv (50 rem) per year and 10% of that value is 50 mSv (5 rem or 5000 millirem) per year. If one of these experiments delivers 0.015 mSv (1.5 mrem),

then an individual could perform 3,333 of these procedures each year and remain within 10% of the applicable limit.

Based on the above specific situation, no dosimetry is required if an individual performs fewer than 1,000 foil activation experiment per year.

Guidance to Licensees

Licensees who wish to demonstrate that they are not required to provide dosimetry to their workers need to perform prospective evaluations similar to that shown in the example above. The expected dose rates, times, and distances used in the above example may not be appropriate to all licensees. In their evaluations, licensees need to use information appropriate to the type(s) of processes they intend to use.

Table I.1 may be helpful in performing a prospective evaluation.

Licensees should review evaluations periodically and revise them as needed. Licensees need to check assumptions used in their evaluations to ensure that they are up-to-date and accurate. For example, if workers become lax in following good radiation safety practices, perform the task more slowly than estimated, utilize a new sealed source containing sources of different activities or radionuclides, or use modified procedures, the licensee would need to conduct a new evaluation.

Table I.1 Dosimetry Evaluation.

Dosimetry Evaluation for_____
A. Time needed to perform the entire routine procedure. _____ minutes/60 = ____ hours
B. Expected whole body dose rate received by the individual. _____ mrem/hr
C. Time the hands were exposed to the radiation source._____ minutes/60 = ____ hours
D. Expected extremity dose rate received by the individual, determined using the measured or manufacturer-provided data for the radiation source at the typical distance from the hands to the source. _____ mrem/hr
Formula: (____ # hours in Row A) x (____ mrem/hr in Row B) = (____ mrem per routine procedure) x (____ # of routine procedures each year) = ___ mrem *Whole Body Dose
Formula: (____ # hours in Row C) x (____ mrem/hr in Row D) = (____ mrem per routine procedure) x (____# of routine procedures each year) = ____ mrem **Extremity Dose

**Expected Whole Body Doses less than 500 mrem does not require dosimetry.*

***Expected Extremity Doses less than 5000 mrem does not require dosimetry.*

Appendix J
Public Dose

This appendix describes different methods for determining radiation doses to members of the public.

Licensees must ensure that:

- To the extent practical, procedures and engineering controls based upon sound radiation protection principles are implemented to achieve doses to members of the public that are as low as reasonably achievable (ALARA).
- The radiation dose received by individual members of the public does not exceed 1 mSv (100 mrem) in one calendar year resulting from the licensee's possession and/or use of licensed materials.
- The radiation dose in unrestricted areas does not exceed 0.02 mSv (2 mrem) in any one hour.
- The air emissions of radioactive materials do not result in doses greater than the constraint limit of 0.1 mSv (10 mrem).

Members of the public include persons who live, work, study, or may be near locations where licensed material is used or stored, and employees whose assigned duties do not include the use of licensed material but may work in the vicinity where such materials are used or stored.

Doses to Members of the Public	
INCLUDES doses from:	DOES NOT INCLUDE doses from:
• Radiation and/or radioactive material released by a licensee • Sources of radiation under the control of a licensee • Air effluents from sources of licensed radioactive materials	• Sanitary sewerage discharges from licensees • Natural background radiation • Medical administration of radioactive material • Voluntary participation in medical research

Typical unrestricted areas may include offices, shops, laboratories (where licensed material is not used or stored), areas outside buildings, property, and storage areas. The licensee does not control access to these areas for purposes of controlling exposure to radiation or radioactive materials, but the licensee may control access to these areas for other reasons, such as security.

Simple Method

The licensee may use any acceptable method from either 10 CFR 20.1302(b)(1) or 10 CFR 20.1302(b)(2) for determining compliance with the annual dose limits in 10 CFR 20.1301. The method described in 10 CFR 20.1302(b)(2) limits the worst-case dose to 1 mSv (0.1 rem). Under this method, the maximum concentration of radionuclides permitted at the unrestricted area boundary would result in a dose to an individual of 0.5 mSv (0.05 rem), and the

dose from external radiation to an individual who is always present to receive the dose would be 0.5 mSv (0.05 rem). This method provides licensees with an easy way to demonstrate compliance without considering occupancy factors or summing of internal and external doses.

Calculation Methods

The licensee may also show compliance with 10 CFR 20.1301 by using the method described in 10 CFR 20.1302(b)(1). This method allows the licensee to take into account the length of time an individual is receiving the dose from external sources and the concentration of radionuclides in gaseous and liquid releases at the location of the individual. In practice, the licensee may wish to make conservative assumptions to simplify the dose calculation. For example, if the actual dose to an individual from external sources plus the maximum possible dose from gaseous and liquid releases is below the public dose limit, the licensee may chose to use this "theoretical" value rather than try to evaluate the exact concentration of radionuclides at the individual's location. If the former calculation is over the limit, the licensee can show compliance by performing the more difficult calculation. If appropriate, the licensee also has the option, with prior NRC approval, of adjusting the dose to take into account the physical and chemical characteristics of its effluent.

Because the dose limit applies to an individual who is likely to receive the highest dose from the licensed operation, dose calculations need to take into account the worst-case scenario in which an individual would be located at the areas of greatest internal and external exposures. The calculation could use an occupancy factor of 1, which means the individual was continuously present 24 hours a day, 365 days a year. If this result shows that the limit is not exceeded, then there is no need for further calculations. If the limit is exceeded with an occupancy factor of 1, then realistic assumptions of how many hours in a 24 hour day an individual would be present at the points of highest internal and external exposures would have to be made. To obtain the occupancy factor, the licensee would take the number of hours of predicted occupancy in a day and divide it by 24 hours, (e.g., 8 hours of predicted occupancy divided by 24 hours would give an occupancy factor of 8/24, or 1/3). Some licensees will require in-depth reviews of their use of radioactive material to obtain appropriate assumptions for the external (and internal) dose rates and occupancy factors.

Survey and Monitoring

Effluent monitoring programs are designed to assess dose rates or concentrations of radionuclides released. Dose rates vary, depending upon the nature of the source and its condition. It may be necessary to provide continuously operating dose-rate meters, or if the source is predictable, it may be adequate to integrate dose rates over periods of time. The mode of discharge of airborne and waterborne effluents will vary from facility to facility. Airborne effluents are most frequently discharged continuously during operations, but the operation itself may be discontinuous, whereas liquid effluents may be discharged continuously or may be stored and subsequently discharged on a batch basis. For each type of source and for each route of potential exposure, consider the location of measurement points, whether continuous monitoring is required, the frequency of sampling and measurement, and any additional information. For discharges of radionuclides, for example, it may be necessary to obtain information on chemical form, concentration, and flow-

rate of the discharge as well as meteorological and hydrological data and other information relating to the receiving environment.

Records

10 CFR 20.2107 requires that the licensee maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public, until the Commission terminates the license. Each licensed operation is different, so the records must be appropriate to each operation. In general, survey and monitoring records of radiation and airborne or waterborne radioactivity should be adequate.

Records of radiation survey results should include a unique identification of instruments used in the survey, name of the surveyors, location and date of survey, reason for the survey, and survey results. Unique identification of the survey instrument allows it to be linked to its calibration and maintenance records. Radiation survey records should also include a description or drawing of the area surveyed, administrative action levels for controlling exposures and evaluations of the impact of measured radiation levels, and documentation of any corrective action taken. Radioactive material release records should contain adequate information to allow reasonable off-site dose assessments to be made in the future. In addition, records should include information on quantities of specific radionuclides and the estimated uncertainty in activity release values, if known.

Radioactivity releases may be determined by effluent monitors or by effluent sampling and subsequent laboratory analysis. For those facilities that use sampling as the primary quantification method, appropriate records for laboratory counting systems should be kept, (e.g., calibration, minimum detectable activity determinations, chi square, resolution, etc.).

Information contained in dose assessment records should include the following, (if applicable):

- Type and energy of radiation involved;
- Physical, chemical and isotopic description of the radioactive material, i.e., gaseous, liquid or particulate, the chemical compound and particle size distribution, if known;
- Total activity released and the method of determination;
- Time and date of the start and end of the release;
- Dilution volume of the effluent stream;
- Identification of the release point, i.e., roof vent, facility stack, drain to the sewer system, etc.;
- Location, identification, and function of the facility surveyed;
- Time and date of surveys;
- Location at which measurements were made, or where liquid and air samples were obtained, either by written description or by sketches;

- Methods and instruments used in measurements, i.e., the method of obtaining the air or water samples;
- Results of the measurements, with the quantities and in the units in which they were obtained (e.g., Sv/h, mSv, R/h, mrem/h, or count/min);
- Dose or activity calculations, including occupancy factors and the assumptions made;
- Statement of conclusions from the survey and whether the findings are in compliance with the regulations;
- Recommendations regarding remedial actions and re-survey;
- Name of the persons performing surveys.

Constraint on Releases of Airborne Radioactive Materials to the Environment

10 CFR Part 20 "Standards for Protection Against Radiation," 10 CFR 20.1302(b) requires that:

- A licensee shall show compliance with the annual dose limit in 10 CFR 20.1301 by: (1) demonstrating by measurement or calculation that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed operation does not exceed the annual dose limit; or (2) demonstrating that (i) the annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area do not exceed the values specified in Table 2 of Appendix B to Part 20; and (ii) if an individual were continuously present in an unrestricted area, the dose from external sources would not exceed 0.002 rem (0.02 mSv) in an hour and 0.05 rem (0.5 mSv) in a year.

In addition, 10 CFR 20.1101(d) requires that:

- To implement the ALARA [as low as is reasonably achievable] requirements of 10 CFR 20.1101(b), and notwithstanding the requirements in 10 CFR 20.1301, a constraint on air emissions of radioactive menial to the environment, excluding radon-222 and its daughters, shall be established by licensees other than those subject to 10 CFR 50.34a, such that the individual member of the public likely to receive the highest dose will not be expected to receive a total effective dose equivalent in excess of 10 mrem (0.1 mSv) per year from these emissions. If a licensee subject to this requirement exceeds this dose constraint, the licensee shall report the exceedance as provided in 10 CFR 20.2203 and promptly take appropriate corrective action to ensure against recurrence.

For further information regarding guidance on compliance with the Constraint Rule, refer to Regulatory Guide 4.20, "Constraint on Releases of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors," issued December 1996.

Appendix K
Surveys

This appendix provides applicants and licensees with additional information on surveys, including training requirements, survey frequency, contamination limits, and bioassays.

Ambient Radiation Level Surveys

- Dose-rate surveys, at a minimum, should be performed in locations where workers are exposed to radiation levels that might result in radiation doses in excess of 10% of the occupational dose limits.
- Dose-rate surveys, at a minimum, should be performed in locations where members of the public could receive a total effective dose equivalent of 1 mSv (100 mrem) in a year, or the dose in any unrestricted area from external sources could exceed 0.02 mSv (2 mrem) in any one hour.
- Dose-rate surveys should be performed in a manner and frequency that is representative of the use of radioactive materials. At a minimum, these surveys should be conducted daily in areas of radioactive material use, where exposures to workers could reasonably occur, (e.g. generator storage/elution and dose preparation stations). Other areas, where radiological conditions are not expected to change appreciably from day-to-day, should be surveyed weekly, (e.g. radioactive waste storage areas).

Contamination Surveys

Licensees' contamination surveys should be sufficient to identify areas of contamination that might result in unacceptable levels of exposure to workers or to the public. Combined removable and fixed contamination should be surveyed using appropriate radiation detection equipment. Removable contamination can be detected and measured through wipe tests, which should be analyzed using an appropriate counting instrument. Fixed contamination may be measured directly at the surface of the contamination with the appropriate instrument detector held at close proximity to the surface without direct contact. See Table H.1 for examples of appropriate instruments.

Contamination surveys should be performed:

- To evaluate radioactive contamination that could be present on surfaces of floors, walls, laboratory furniture, or equipment;
- After any spill or contamination event;
- To evaluate contamination of users and the immediate work area at the end of each day when licensed material is used;
- In unrestricted areas at frequencies consistent with the types and quantities of materials in use;
- In areas adjacent to restricted areas and in all areas through which licensed materials are transferred and temporarily stored before shipment.

Contamination Survey Frequency

All areas where radioactive materials are eluted, prepared, assayed, dispensed, or packaged for transport should be surveyed daily. All other areas where radioactive materials are used or stored should be surveyed weekly.

Contamination in Unrestricted Areas

Contamination found in unrestricted areas should be immediately decontaminated to background levels. When it is not possible to get to background levels, the licensee must ensure that the amounts do not exceed the contamination levels listed in Table K.1.

Table K.1 Recommended Action Levels for Surface Contamination.

	P-32, Se-75, Sr-85, Sr-89, In-111, I-123, I-125, I-131, Sm-153, Yb-169, Re-186, Au-198, Cr-51, Ga-67, Tc-99m, Tl-201, Natural Uranium, U-235, U-238 and associated decay products, Plutonium			
	Type of Radioactive Material			
	Beta – Gamma ($dpm/100cm^2$)		**Alpha ($dpm/100cm^2$)**	
	Removable	**Fixed**	**Removable**	**Fixed**
1. Unrestricted areas, personal clothing	200	2,000	20	1,000
2. Restricted areas, protective clothing used only in restricted areas, skin	2,000	20,000	200	10,000

When equipment or facilities that are potentially contaminated are to be released for unrestricted use, Row 1 of the above table provides the maximum acceptable residual levels. Where both alpha and beta-gamma emitting nuclides exist, the limits established for alpha and beta-gamma emitting nuclides should be applied independently. To the extent practicable, it is appropriate to decontaminate below these levels. Surface contamination surveys should be conducted for both removable and fixed contamination before these facilities or equipment are released.

A standardized method for wipe testing of a relatively uniform area should be used to aid in comparing contamination at different times and places. A wipe taken from an area of approximately 100 cm^2 is acceptable to indicate levels of removable contamination.

Survey Record Requirements

Each survey record should include the following:

- Diagram of the area identifying specific locations surveyed;
- Ambient radiation levels with appropriate units;
- Contamination levels with appropriate units;
- Make and model number of instruments used;
- Background levels;
- Name of the person making the evaluation and recording the results and date;
- Corrective actions taken for elevated levels identified and results of repeated surveys.

Licensees should record contamination levels observed and procedures followed for incidents involving contamination of individuals. The record should include names of individuals involved, description of work activities, calculated dose, probable causes (including root causes), steps taken to reduce recurrence of contamination, times and dates, and surveyor's signature.

Air Sampling

Air sampling can be used to do the following:

- Determine whether the confinement of radioactive materials is effective;
- Measure airborne radioactive material concentrations in the workplace;
- Estimate worker intakes of radioactive material;
- Determine posting requirements;
- Determine what protective equipment and measures are appropriate;
- Warn of significantly elevated levels of airborne radioactive materials.

Refer to Regulatory Guide 8.25, Revision 1, "Air Sampling in the Workplace," dated June 1992, and NUREG-1400, "Air Sampling in the Workplace," dated September 1993, for further guidance on air sampling.

Air Effluent Monitoring

Airborne radioactive effluents should be monitored at the release points (e.g., stack) to provide accurate measurements to estimate public exposure. Licensees should verify the performance of effluent monitoring systems by regular calibration of equipment and checks of filtration to ensure their reliability.

Regulatory Guide 4.20, "Constraints on Release of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors," dated December 1996, provides

guidance on methods acceptable (calculation or COMPLY code) to NRC for compliance with the constraint on air emissions to the environment.

Regulatory Guide 8.37, "ALARA Levels for Effluents from Materials Facilities," dated July 1993, provides guidance on designing an acceptable program for establishing and maintaining ALARA levels for gaseous and liquid effluents at materials facilities.

Effluent monitoring systems should be designed in accordance with ANSI N13.1 (1969), "Document to Sampling Airborne Radioactive Materials in Nuclear Facilities," and ANSI N42.18, "Specification and Performance of On-site Instrumentation for Continuously Monitoring Radioactive Effluents."

Sanitary Sewerage Release Monitoring

The licensee should evaluate the concentrations of radioactive material in water that is released to the environment and to the sanitary sewer. The licensee must show that these releases meet the limits in 10 CFR 20. 1301 and 20.2003, respectively.

Special Monitoring

Because of uncertainty in the time of intakes and the absence of other data related to the exposure (e.g., physical and chemical forms, exposure duration), correlating positive results to actual intakes for routine measurements can sometimes be difficult. Abnormal and inadvertent intakes from situations such as inadequate engineering controls, inadvertent ingestion, contamination of a wound, or skin absorption, should be evaluated on a case-by-case basis. When determining whether potential intakes should be evaluated, consider the following circumstances:

- Presence of unusually high levels of facial and/or nasal contamination;
- Operational events with a reasonable likelihood that a worker was exposed to unknown quantities of airborne radioactive material (e.g., loss of system or container integrity);
- Known or suspected incidents of a worker ingesting radioactive material;
- Incidents that result in contamination of wounds or other skin absorption;

1. Regulatory Guide 4.20, "Constraints on Release of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors," dated December 1996.
2. Regulatory Guide 8.9, Revision 1, "Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program," dated July 1993.
3. Regulatory Guide 8.25, Revision 1, "Air Sampling in the Workplace," dated June 1992.
4. Regulatory Guide 8.37, " ALARA Levels for Effluents from Materials Facilities," dated July 1993.
5. NUREG-1400, "Air Sampling in the Workplace," dated September 1993.
6. NUREG/CR-4884, "Interpretation of Bioassay Measurements," dated July 1987.

7. ANSI N13.1 (1969), "Document to Sampling Airborne Radioactive Materials in Nuclear Facilities," dated 1991.
8. ANSI N42.18, "Specification and Performance of On-site Instrumentation for Continuously Monitoring Radioactive Effluents," dated 1991.

- Many NRC documents can be accessed from the following Internet address: <http://www.nrc.gov>.

Appendix L
Model Leak Test Program

Training

Before allowing an individual to perform leak testing, the RSO will ensure that he or she has sufficient classroom and on-the-job training to show competency in performing leak tests independently.

Classroom training may be in the form of lecture, videotape, hands-on, or self-study and will cover the following subject areas:

- Principles and practices of radiation protection;
- Radioactivity measurements, monitoring techniques, and using instruments;
- Mathematics and calculations basic to using and measuring radioactivity;
- Biological effects of radiation.

Appropriate on-the-job-training consists of:

- Observing authorized personnel collecting and analyzing leak test samples;
- Collecting and analyzing leak test samples under the supervision and in the physical presence of an individual authorized to perform leak tests.

Facilities and Equipment

- To ensure achieving the required sensitivity of measurements, leak tests will be analyzed in a low-background area.
- Individuals conducting leak tests will use a calibrated and operable survey instrument to check leak test samples for gross contamination before they are analyzed. If the sensitivity of the counting system is unknown, the minimum detectable activity (MDA) needs to be determined. The MDA may be determined using the following formula:

$$MDA = \frac{2.71 + 4.65\sqrt{(B_R \times t)}}{t \times E} = \textit{Minimum Detectable Activity}$$

where MDA = activity level in disintegrations per minute

B_R = background rate in counts per minute

t = counting time in minutes

E = detector efficiency in counts per disintegration

For example:

BR = 200 counts per minute
E = 0.1 counts per disintegration (10% efficient)
t = 2 minutes

$$MDA = \frac{2.71 + 4.65\sqrt{(200 \times 2)}}{2 \times 0.1} = \frac{2.71 + 4.65\sqrt{(400)}}{0.2}$$

$$= \frac{2.71 + 4.65\,(20)}{0.2} = \frac{2.71 + 93}{0.2} = \frac{95.71}{0.2}$$

$$= \frac{4785.5\ \textit{disintegrations}}{\textit{minute}}$$

$$\textit{becquerels (Bq)} = \frac{1\ \textit{disintegration}}{\textit{second}}$$

$$Bq = \frac{4785.5\ \textit{disintegrations}}{\textit{minutes}} + \frac{\textit{minute}}{60\ \text{seconds}} = 79.76 \approx 80\ Bq$$

Frequency for Conducting Leak Tests of Sealed Sources

- Leak tests will be conducted at the frequency specified in the respective SSD Registration Certificate.

Procedure for Performing Leak Testing and Analysis

- For each source to be tested, list identifying information such as serial number, radionuclide, activity or quantity.
- Prepare a separate wipe sample (e.g., cotton swab or filter paper) for each source.
- Number each wipe to correlate with identifying information for each source.
- Wipe the most accessible area where contamination would accumulate if the sealed source were leaking.
- Select an instrument that is sensitive enough to detect 185 Bq (0.005 microcurie) of the radionuclide.
- Using the selected instrument, count and record background count rate.
- Check the instrument's counting efficiency using a standard source of the same radionuclide as the source being tested or one with similar energy characteristics. Accuracy of standards should be within ±5% of the stated value and traceable to primary radiation standards such as those maintained by NIST.

- Calculate efficiency.

  For example: $\frac{[(\text{cpm from std}) - (\text{cpm from bkg})}{\text{activity of std in Bq}} = \text{efficiency in cpm/Bq}$

  where: cpm = counts per minute
  std = standard
  bkg = background
  Bq = Becquerel

- Count each wipe sample; determine net count rate.
- For each sample, calculate and record estimated activity in Bq (or microcuries).

  For example: $\frac{[(\text{cpm from wipe sample}) - (\text{cpm from bkg})]}{\text{efficiency in cpm/Bq}} = \text{Bq on wipe sample}$

- Sign and date the list of sources, data, and calculations. Retain records for 3 years (10 CFR 20.2103(a)).
- If the wipe test activity is 185 Bq (0.005 microcurie) or greater, notify the RSO, so that the source can be withdrawn from use and disposed of properly. Also notify NRC.

Reference: See the Notice of Availability (on the inside front cover of this report) to obtain a copy of Draft RG FC 412-4, "Guide for the Preparation of Applications for Licenses for the Use of Radioactive Materials in Leak-Testing Services," dated June 1985.

Appendix M
Transportation
Part 1:
Major DOT Regulations

Transportation

The major areas in the DOT regulations that are most relevant for transportation of licensed material shipped as Type A quantities are as follows:

- Hazardous Materials Table, 49 CFR 172.101, App. A, list of hazardous substances and reportable quantities (RQ), Table 2: Radionuclides;
- Shipping Papers 49 CFR 172.200-204: General entries, description, additional description requirements, shipper's certification;
- Package Markings 49 CFR 172.300, 49 CFR 172.301, 49 CFR 172.303, 49 CFR 172.304, 49 CFR 172.310, 49 CFR 172.324: General marking requirements for non-bulk packaging, prohibited marking, marking requirements, radioactive material, hazardous substances in non-bulk packaging;
- Package Labeling 49 CFR 172.400, 49 CFR 172.401, 49 CFR 172.403, 49 CFR 172.406, 49 CFR 172.407, 49 CFR 172.436, 49 CFR 172.438, 49 CFR 172.440: General labeling requirements, prohibited labeling, radioactive materials, placement of labels, specifications for radioactive labels;
- Placarding of Vehicles 49 CFR 172.500, 49 CFR 172.502, 49 CFR 172.504, 49 CFR 172.506, 49 CFR 172.516, 49 CFR 172.519, 49 CFR 172.556: Applicability, prohibited and permissive placarding, general placarding requirements, providing and affixing placards: highway, visibility and display of placards, specifications for RADIOACTIVE placards;
- Emergency Response Information, Subpart G, 49 CFR 172.600, 49 CFR 172.602, 49 CFR 172.604: Applicability and general requirements, emergency response information, emergency response telephone number;
- Training, Subpart H, 49 CFR 172.702, 49 CFR 172.704: Applicability and responsibility for training and testing, training requirements;
- Shippers - General Requirements for Shipments and Packaging, Subpart I, 49 CFR 173.403, 49 CFR 173.410, 49 CFR 173.412, 49 CFR 173.415, 49 CFR 173.431, 49 CFR 173.433, 49 CFR 173.435, 49 CFR 173.441, 49 CFR 173.443, 49 CFR 173.448, 49 CFR 173.475, 49 CFR 173.476: Definitions, general design requirements, additional design requirements for Type A packages, authorized Type A packages, activity limits for Type A... packages, requirements for determining A_1 and A_2, table of A_1 and A_2 values for radionuclides, radiation level limitations, contamination control, general transportation requirements, quality control requirements prior to each shipment, approval of special form radioactive materials;
- Radiation Protection Program for Shippers and Carriers, Subpart I, 49 CFR 172.801, 49 CFR 172.803, 49 CFR 172.805: Applicability of the radiation protection program, radiation protection program, record keeping, and notifications;
- Carriage by Public Highway - General Information and Regulations, Subpart A, 49 CFR 177.816, 49 CFR 177.817, 49 CFR 177.834(a), 49 CFR 177.842: Driver training,

shipping paper, general requirements (secured against movement), Class 7 (radioactive) material.

Appendix M
Transportation
Part 2
Sample Shipping Documents, Placards and Labels

Hazard Communications for Class 7 (Radioactive) Materials

DOT Shipping Papers (49 CFR 172.200-205)

NOTE: IAEA, ICAO, and IMO may require additional hazard communication information for international shipments
This table must not be used as a substitute for the DOT and NRC regulations on the transportation of radioactive materials

Entries Always Required Unless Excepted	Additional Entries Sometimes Required	Optional Entries
• The basic description, In sequence: **Proper Shipping Name, Hazard Class (7), U.N. Identification Number** • 24 hour **emergency response telephone number** • Name of **shipper** • Proper page numbering (Page 1 of 4) • Except for empty and bulk packages, the **total quantity** (mass, or volume for liquid), in appropriate units (lbs, mL....) • If not special form, **chemical and physical form** • The **name of each Radionuclides** (95% rule) and total package activity. The activity must be in SI units (e.g., Bq, TBq), or both SI units and customary units (e.g., Ci, mCi). • For each labeled package: - The **category of label** used; - The **transport index** of each package with a Yellow-II or Yellow-III label • Shipper's **certification** (not required of private carriers)	Materials-Based Requirements: • If hazardous substance, "RQ" as part of the basic description • The LSA or SCO group (e.g., LSA-II) • "Highway Route Controlled Quantity" as part of the basic description , if HRCQ • Fissile material information (e.g., "Fissile Exempt," controlled shipment statement [see §172.203(d)(7)]) • If the material is considered hazardous waste and the word waste does not appear in the shipping name, then "waste" must precede the shipping name (e.g., Waste Radioactive Material, nos, UN2982) • "Radioactive Material" if not in proper shipping name Package-Based Requirements: • Package identification for DOT Type B or NRC certified packages • IAEA CoC ID number for export shipments or shipments using foreign-made packaging (see §173.473) Administrative-Based Requirements: • "Exclusive Use-Shipment" • Instructions for maintenance of exclusive use-shipment controls for LSA/SCO strong-tight or NRC certified LSA (§ 173.427) • If a DOT exemption is being used, "DOT-E" followed by the exemption number	• The type of packaging (e.g., Type A, Type B, IP-1, ...) • The Technical/chemical name may be in included (if listed in §172.203(k), in parentheses between the proper shipping name and hazard class; otherwise inserted in parenthesis after the basic description) • Other information is permitted (e.g., functional description of the product), provided it does not confuse or detract from the proper shipping name or other required information • For fissile radionuclides, except Pu-238, Pu-239, and Pu-241, the weight in grams or kilograms may be used *in place of* activity units. For Pu-238, Pu-239, and Pu-241, the weight in grams or kilograms may optionally be entered *in addition to* activity units [see § 172.203(d)(4)] • Emergency response hazards and guidance information (§§ 172.600-604) may be entered on the shipping papers, or may be carried with the shipping papers [§ 172.602(b)]

Some Special Considerations/Exceptions for Shipping Paper Requirements

- Shipments of Radioactive Material, excepted packages, under UN2910 (e.g., Limited Quantity, Empty packages, and Radioactive Instrument and Article), are excepted from shipping papers. For limited quantities (§173.421), this is only true if the limited quantify is not a hazardous substance (RQ) or hazardous waste (40 CFR 262)
- Shipping papers must be in the pocket on the left door, or readily visible to person entering driver's compartment and within arm's reach of the driver
- For shipments of multiple cargo types, any HAZMAT entries must appear as the first entries on the shipping papers, be designated by an "X" (or "RQ") in the hazardous material column, or be highlighted in a contrasting color

Hazard Communications for Class 7 (Radioactive) Materials

Marking Packages (49 CFR 172.300-338)

NOTE: IAEA, ICAO, and IMO may require additional hazard communication information for international shipments

This table must not be used as a substitute for the DOT and NRC regulations on the transportation of radioactive materials

Markings Always Required Unless Excepted	Additional Markings Sometimes Required	Optional Markings
Non-Bulk Packages • Proper shipping name -U.N. identification number • Name and address of consignor or consignee, *unless*: - highway only and no motor carrier transfers, or - part of carload or truckload lot or freight container load, and entire contents of railcar, truck, or freight container are shipped from one consignor to one consignee [see §172.301(d)] Bulk Packages (i.e., net capacity greater than 119 gallons as a receptacle for liquid, or 119 gallons and 882 pounds as a receptacle for solid, or water capacity greater than 1000 lbs, with no consideration of intermediate forms of containment) • U.N. identification number, on orange, rectangular panel (see §172.332) - some exceptions exist	Materials-Based Requirements: • If in excess of 110 lbs (50 kg), Gross Weight • If non-bulk liquid package, underlined double arrows indicating upright orientation (two opposite sides) [ISO Std 780-1985 marking] • If a Hazardous substance in non-bulk package, the letters "RQ" in association with the proper shipping name Package-Based Requirements: • The package type if Type A or Type B (½" or greater letters) • The specification-required markings [e.g., for Spec. 7A packages: "DOT 7A Type A" and "Radioactive Material" (see §178.350-353)] • For approved packages, the certificate ID number (e.g., USA/9166/B(U), USA/9150/B(U)-85, ...) • If Type B, the trefoil (radiation) symbol per Part 172 App. B [*size*: outer radius ≥ 20 mm (0.8 in)] • For NRC certified packages, the model number, gross weight, and package ID number (10 CFR 71.85) Administrative-Based Requirements: • If a DOT exemption is being used, "DOT-E" followed by the exemption number • If an export shipment, "USA" in conjunction with the specification markings or certificate markings	• "IP-1," "IP-2," or "IP-3" on industrial packaging is recommended • Both the name and address of consignor and consignee are recommended • Other markings (e.g., advertising) are permitted, but must be sufficiently away from required markings and labeling

Some Special Considerations/Exceptions for Marking Requirements

- Marking is required to be: (1) durable, (2) printed on a package, label, tag, or sign, (3) unobscured by labels or attachments, (4) isolated from other marks, and (5) be representative of the HAZMAT contents of the package
- Limited Quantity (§173.421) packages and Articles Containing Natural Uranium and Thorium (§173.426) must bear the marking "radioactive" on the outside of the inner package or the outer package itself, and are excepted from other marking. The excepted packages shipped under UN 2910 must also have the accompanying statement that is required by §173.422.
- Empty (§173.428) and Radioactive Instrument and Article (§173.424) packages are excepted from marking
- Shipment of LSA or SCO required by §173.427 to be consigned as exclusive use are excepted from marking except that the exterior of each nonbulk package must be marked "**Radioactive-LSA**" or "**Radioactive-SCO**," as appropriate. Examples of this category are domestic, strong-tight containers with less than an A_2 quantity, and domestic NRC certified LSA/SCO packages using 10 CFR 71.52.
- For bulk packages, marking may be required on more than one side of the package (see 49 CFR 172.302(a))

Hazard Communications for Class 7 (Radioactive) Materials

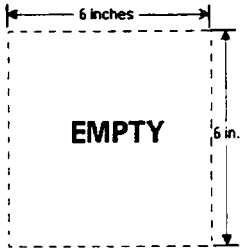
Labeling Packages (49 CFR 172.400-450)

NOTE: IAEA, ICAO, and IMO may require additional hazard communication information for international shipments
This table must not be used as a substitute for the DOT and NRC regulations on the transportation of radioactive materials

Placement of Radioactive Labels

- Labeling is required to be: (1) placed near the required marking of the proper shipping name, (2) printed or affixed to the package surface (not the bottom), (3) in contrast with its background, (4) unobscured by markings or attachments, (5) within color, design, and size tolerance, and (6) representative of the HAZMAT contents of the package
- For labeling of radioactive materials packages, two labels are required on opposite sides excluding the bottom

Determination of Required Label

Size: *Sides:* ≥ 100 mm (3.9 in.) *Border:* 5-6.3 mm (0.2-0.25 in.)	 49 CFR 172.436	 49 CFR 172.438	 49 CFR 172.440	 49 CFR 172.450
Label	**WHITE-I**	**YELLOW-II**	**YELLOW-III**	**EMPTY LABEL**
Required when:	Surface radiation level < 0.005 mSv/hr (0.5 mrem/hr)	0.005 mSv/hr (0.5 mrem/hr) < surface radiation level ≤ 0.5 mSv/hr (50 mrem/hr)	0.5 mSv/hr (50 mrem/hr) < surface radiation level ≤ 2 mSv/hr (200 mrem/h) [Note: 10 mSv/hr (1000 mrem/hr) for exclusive-use closed vehicle (§173.441(b)]	The EMPTY label is required for shipments of empty Class 7 (radioactive) packages made pursuant to **§173.428**. It must cover any previous labels, or they must be removed or obliterated.
Or:	**TI = 0** [1 meter dose rate < 0.0005 mSv/hr (0.05 mrem/hr)]	**TI ≤ 1** [1 meter dose rate < 0.01 mSv/hr (1 mrem/hr)]	**TI ≤ 10** [1 meter dose rate < 0.1 mSv/hr (10 mrem/hr)] [Note: There is no *package* TI limit for exclusive-use]	
Notes:	• Any package containing a Highway Route Controlled Quantity **(HRCQ) must bear YELLOW-III label** • Although radiation level transport indices (TIs) are shown above, **for fissile material**, the TI is typically determined on the basis of criticality control			

Content on Radioactive Labels

- RADIOACTIVE Label must contain (entered using a durable, weather-resistant means):
  (1) The radionuclides in the package (with consideration of available space). Symbols (e.g., Co-60) are acceptable
  (2) The activity in SI units (e.g., Bq, TBq), or both SI units with customary units (e.g., Ci, mCi) in parenthesis.
  (3) The Transport Index (TI) in the supplied box. The TI is entered *only* on YELLOW-II and YELLOW-III labels

Some Special Considerations/Exceptions for Labeling Requirements

- For materials meeting the definition of another hazard class, labels for each secondary hazard class need to be affixed to the package. The subsidiary label *may* not be required on opposite sides, and must not display the hazard class number
- Radioactive Material, excepted packages, under UN2910 (e.g., Limited Quantity, Empty packages, and Radioactive Instrument and Article), are excepted from labeling. However, if the excepted quantity meets the definition for another hazard class, it is re-classed for that hazard. Hazard communication requirements for the other class are required
- Labeling exceptions exist for shipment of LSA or SCO required by § 173.427 to be consigned as exclusive use
- The "Cargo Aircraft Only" label is typically required for radioactive materials packages shipped by air [§ 172.402(c)]

Hazard Communications for Class 7 (Radioactive) Materials

Placarding Vehicles (49 CFR 172.500-560)

NOTE: IAEA, ICAO, and IMO may require additional hazard communication information for international shipments
This table must not be used as a substitute for the DOT and NRC regulations on the transportation of radioactive materials

Visibility and Display of Radioactive Placard

- Placards are required to be displayed:
  - on four sides of the vehicle
  - visible from the direction they face, (for the front side of trucks, tractor-front, trailer, or both are authorized)
  - clear of appurtenances and devices (e.g., ladders, pipes, tarpaulins)
  - at least 3 inches from any markings (such as advertisements) which may reduce placard's effectiveness
  - upright and on-point such that the words read horizontally
  - in contrast with the background, or have a lined-border which contrasts with the background
  - such that dirt or water from the transport vehicle's wheels will not strike them
  - securely attached or affixed to the vehicle, or in a holder.
- Placard must be maintained by carrier to keep color, legibility, and visibility.

Conditions Requiring Placarding

- Placards are required for any vehicle containing package with a RADIOACTIVE Yellow-III label
- Placards are required for shipment of LSA or SCO required by §173.427 to be consigned as exclusive use. Examples of this category are domestic, strong-tight containers with less than an A_2 quantity, and domestic NRC certified LSA/SCO packages using 10 CFR 71.52. Also, for bulk packages of these materials, the orange panel *marking* with the UN Identification number is not required.
- Placards are required any vehicle containing package with a Highway Route Controlled Quantity **(HRCQ)**. In this case, the placard must be placed in a square background as shown below (see §173.507(a))

Radioactive Placard

Size Specs:			
Sides: ≥ 273 mm (10.8 in.) *Solid line Inner border:* About 12.7 mm (0.5 in.) from edges *Lettering:* ≥ 41 mm (1.6 in.) *Square for HRCQ:* 387mm (15.25 in.) outside length by 25.4 mm (1 in.) thick	 49 CFR 172.556	 IAEA SS 6 (1985) paras. 443-444	 See 49 CFR 172.527 AND 556
	RADIOACTIVE PLACARD (Domestic) *Base of yellow solid area:* 29 ± 5 mm (1.1 ± 0.2 in.) above horizontal centerline	**RADIOACTIVE PLACARD (International)**	**RADIOACTIVE PLACARD FOR HIGHWAY ROUTE CONTROLLED QUANTITY** (either domestic or international placard could be in middle)

Some Special Considerations/Exceptions for Placarding Requirements

- Domestically, substitution of the UN ID number for the word "RADIOACTIVE" on the placard is prohibited for Class 7 materials. However, some import shipments may have this substitution in accordance with international regulations.
- Bulk packages require the orange, rectangular panel marking containing the UN ID number, which must be placed adjacent to the placard (see §172.332) [NOTE: except for LSA/ SCO exclusive use under §173.427, as above]
- If placarding for more than one hazard class, subsidiary placards must not display the hazard class number. Uranium Hexafluoride (UF_6) shipments ≥ 454 kg (1001 lbs) require both RADIOACTIVE and CORROSIVE (Class 8) placarding
- For shipments of radiography cameras in convenience overpacks, if the overpack does not require a RADIOACTIVE - YELLOW III label, vehicle placarding is not required (regardless of the label which must be placed on the camera)

Minimum Required Packaging For Class 7 (Radioactive) Materials
This table must not be used as a substitute for the DOT and NRC regulations on the transportation of radioactive materials

Quantity:	< 70 Bq/g (< 0.002 :Ci/g)	Limited Quantity (§173.421)	A_1/A_2 value (§173.435)	1 rem/hr at 3 m, unshielded (§173.427)
Non-LSA/SCO:	**Excepted**	**Type A**	**Type B [3]**	
Domestic or International LSA/SCO: LSA-I solid, (liquid)[1] SCO-I	**Excepted**	**IP-I**		**Type B [3]**
LSA-I Liquid LSA-II Solid, (liquid or gas)[1] (LSA-III)[1] SCO-II		**IP-II**		**Type B [3]**
LSA-II Liquid or Gas LSA-III		**IP-III**		**Type B [3]**
Domestic (only) LSA/SCO: LSA-I, II, III; SCO-I, II	**Excepted**	**Strong-tight [2]**	**DOT Spec. 7A Type A**	**Type B [3]** **NRC Type A LSA [3,4]**

1. For entries in parentheses, exclusive use is required for shipment in an IP (e.g., shipment of LSA-I liquid in an IP-I packaging would require exclusive use consignment)
2. Exclusive use required for strong-tight container shipments made pursuant to §173.427(b)(2)
3. Subject to conditions in Certificate, if NRC package
4. Exclusive use required, see §173.427(b)(4). Use of these packages expires on 4/1/99 (10 CFR 71.52)

Package and Vehicle Radiation Level Limits (49 CFR 173.441) [A]
This table must not be used as a substitute for the DOT and NRC regulations on the transportation of radioactive materials

Transport Vehicle Use:	**Non-Exclusive**	**Exclusive**		
Transport Vehicle Type:	Open or Closed	Open (flat-bed)	Open w/Enclosure [B]	Closed
Package (or freight container) **Limits:**				
External Surface	2 mSv/hr **(200 mrem/hr)**	2 mSv/hr **(200 mrem/hr)**	10 mSv/hr **(1000 mrem/hr)**	10 mSv/hr **(1000 mrem/hr)**
Transport Index (TI) [C]	10	no limit		
Roadway or Railway Vehicle (or freight container) **Limits:**				
Any point on the outer surface	N/A	N/A	N/A	2 mSv/hr **(200 mrem/hr)**
Vertical planes projected from outer edges		2 mSv/hr **(200 mrem/hr)**	2 mSv/hr **(200 mrem/hr)**	N/A
Top of...		load: **(200 mrem/hr)**	enclosure: 2 mSv/hr **(200 mrem/hr)**	vehicle: 2 mSv/hr **(200 mrem/hr)**
2 meters from. . .		vertical planes: 0.1 mSv/hr **(10 mrem/hr)**	vertical planes: 0.1 mSv/hr **(10 mrem/hr)**	outer lateral surfaces: 0.1 mSv/hr **(10 mrem/hr)**
Underside		2 mSv/hr **(200 mrem/hr)**		
Occupied position	N/A [D]	0.02 mSv/hr **(2 mrem/hr)** [E]		
Sum of package TI's	50	no limit [F]		

A. The limits in this table do not apply to excepted packages - see 49 CFR 173.421-426
B. Securely attached (to vehicle), access-limiting enclosure; package personnel barriers are considered as enclosures
C. For nonfissile radioactive materials packages, the dimensionless number equivalent to maximum radiation level at 1 m (3.3 feet) from the exterior package surface, in millirem/hour
D. No dose limit is specified, but separation distances apply to Radioactive Yellow-II or Radioactive Yellow-III labeled packages
E. Does not apply to private carrier wearing dosimetry if under radiation protection program satisfying 10 CFR 20 or 49 CFR 172 Subpart I
F. Some fissile shipments may have combined conveyance TI limit of 100 - see 10 CFR 71.59 and 49 CFR 173.457

Package and Vehicle Contamination Limits (49 CFR 173.443)
This table must not be used as a substitute for the DOT and NRC regulations on the transportation of radioactive materials

NOTE: All values for contamination in DOT rules are to be averaged over each 300 cm^2
Sufficient measurements must be taken in the appropriate locations to yield representative assessments

&(means the sum of beta emitters, gamma emitters, and low-toxicity alpha emitters
" means the sum of all other alpha emitters (i.e., other than low-toxicity alpha emitters)

The Basic Contamination Limits for All Packages: 49 CFR 173.443(a), Table 11	**General Requirement: Non-fixed (removable) contamination must be kept as low as reasonably achievable (ALARA)**
	&(: 0.4 Bq/cm^2 = 40 Bq/100 cm^2 = $1x10^{-5}$:Ci/cm^2 = 2200 dpm/100 cm^2
	": 0.04 Bq/cm^2 = 4 Bq/100 cm^2 = $1x10^{-6}$:Ci/cm^2 = 220 dpm/100 cm^2

The following exceptions and deviations from the above basic limits exist:

Deviation from Basic Limits	**Regulation 49 CFR §§**	**Applicable Location and Conditions Which must Be Met:**
10 times the basic limits	173.443(b) and 173.443(c) Also see 177.843 (highway)	On any external surface of a package in an **exclusive use shipment, during transport** including end of transport. Conditions include: (1) Contamination levels at beginning of transport must be below the basic limits. (2) Vehicle must not be returned to service until radiation level is shown to be ≤ 0.005 mSv/hr (0.5 mrem/hr) at any accessible surface, and there is no significant removable (non-fixed) contamination.
10 times the basic limits	173.443(d) Also see 177.843 (highway)	On any external surface of a package, at the beginning or end of transport, if a closed transport vehicle is used, solely for transporting radioactive materials packages. Conditions include: (1) A survey of the interior surfaces of the empty vehicle must show that the radiation level at any point does not exceed 0.1 mSv/hr (10 mrem/hr) at the surface, or 0.02 mSv/hr (2 mrem/hr) at 1 meter (3.3 ft). (2) Exterior of vehicle must be conspicuously stenciled, **"For Radioactive Materials Use Only"** in letters at least 76 mm (3 inches) high, on both sides. (3) Vehicle must be kept closed except when loading and unloading.
100 times the basic limits	173.428	**Internal** contamination limit for **excepted package-empty packaging**, Class 7 (Radioactive) Material, shipped in accordance with 49 CFR 173.428. Conditions include: (1) The basic contamination limits (above) apply to **external** surfaces of package. (2) Radiation level must be ≤ 0.005 mSv/hr (0.5 mrem/hr) at any external surface. (3) Notice in §173.422(a)(4) must accompany shipment. (4) Package is in unimpaired condition & securely closed to prevent leakage. (5) Labels are removed, obliterated, or covered, and the "empty" label (§172.450) is affixed to the package.

In addition, **after any incident** involving spillage, breakage, or suspected contamination, the modal-specific DOT regulations (§177.861(a), highway; §174.750(a), railway; and §175.700(b), air) specify that vehicles, buildings, areas, or equipment have "no significant removable surface contamination," before being returned to service or routinely occupied. The carrier must also notify offer or at the earliest practicable moment after incident.

Example Certificate Enclosed In/or on Package, Included with the Packing List or Otherwise Forwarded with the Package

This package conforms to the conditions and limitations specified in 49 CFR 173.424 for radioactive material, excepted package-instruments or articles, UN2910.

_____

(Signed) Radiation Safety Officer

Appendix N
Sample License

NRC FORM 374

U.S. NUCLEAR REGULATORY COMMISSION

PAGE 1 OF 3 PAGES

Amendment No.

Licwater

MATERIALS LICENSE

CORRECTED COPY

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	In accordance with the dated
1. University of Special Nuclear Material	3. License number SNM-XXXX is amended in its entirety to read as follows:
2. 1039 Howitzer Blvd. P.O. Box 418 Anytown, U.S.A. 44449	4. Expiration date July 31, 2009 5. Docket No. 070-01234 Reference No.

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
11. Plutonium-239	1. Sealed Pu-Be neutron sources	A. 32 grams
B. Plutonium-238/239	B. Plated alpha sources	B. Not to exceed 50 micrograms per plated source and 3 grams total
C. Any byproduct material	C. Activation products	C. See Item 9.C.

9. Authorized use:

A. To be used in a Manufacturer Model Z-707 neutron howitzer for laboratory experiments and student instruction.

B. Alpha standards for calibration and reference purposes.

C. Possession incident to the performance of irradiation experiments utilizing the Pu-Be source. To be used for student instruction.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at Alpha Hall, University of Special Nuclear Material,1039 Howitzer Blvd., Anytown, U.S.A.

NRC FORM 374A U.S. NUCLEAR REGULATORY COMMISSION	PAGE 2 of 3 PAGES
MATERIALS LICENSE **SUPPLEMENTARY SHEET**	License Number SNM-XXXX Docket or Reference Number 070-01234 Amendment No. CORRECTED COPY

11. A. Licensed material shall be used by, or under the supervision of, James J. Curie, Paul D. Neutron and William Grams, Ph.D.

    B. The Radiation Safety Officer for this license is William Grams, Ph.D.

12. A. Sealed sources and detector cells shall be tested for leakage and/or contamination at intervals not to exceed 6 months or at such other intervals as specified by the certificate of registration referred to in 10 CFR 32.210.

    B. Notwithstanding Paragraph A of this Condition, sealed sources designed to emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.

    C. In the absence of a certificate from a transferor indicating that a leak test has been made within 6 months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.

    D. Sealed sources need not be leak tested if:

        (i) they contain only hydrogen-3; or

        (ii) they contain only a radioactive gas; or

        (iii) the half-life of the isotope is 30 days or less; or

        (iv) they contain not more than 100 microcuries of beta and/or gamma emitting material or not more than 10 microcuries of alpha emitting material; or

        (v) they are not designed to emit alpha particles, are in storage, and are not being used. However, when they are removed from storage for use or transferred to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source or detector cell shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

    E. The leak test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(b)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region III, ATTN: Chief, Nuclear Materials Safety Branch, 801 Warrenville Road, Lisle, Illinois 60532-4351. The report shall specify the source involved, the test results, and corrective action taken.

    F. Tests for leakage and/or contamination shall be performed by the licensee or by other persons specifically licensed by the Commission or an Agreement State to Perform such services.

NRC FORM 374A U.S. NUCLEAR REGULATORY COMMISSION	PAGE 3 of 3 PAGES
MATERIALS LICENSE **SUPPLEMENTARY SHEET**	License Number SNM-XXXX Docket or Reference Number 070-01234 Amendment No. **CORRECTED COPY**

13. Sealed sources containing licensed material shall not be opened.

14. License material shall not be used in or on human beings.

15. Except for plutonium contained in a medical device designed for individual human application, no plutonium, regardless of form, shall be delivered to a carrier for shipment by air transport or transported in an aircraft by the licensee except in packages the design of which NRC has specifically approved for transport of plutonium by air.

16. The licensee shall conduct a physical inventory every 6 months to account for all sources and/or devices received and possessed under the license.

17. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

    A. Application dated January 27, 1999 (with attachments).

    B. Letters dated February 14, 1999 and March 26, 1999.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

(insert license issue date)
Date _____

(Insert reviewer name) (Original signed by)
By _____
NRC License Reviewer

Materials Licensing Branch
Region III

Appendix O
NRC Incident Notifications

Table O.1 Typical NRC Incident Notifications Required for Licensees.

Event	Telephone Notification	Written Report	Regulatory Requirements
Theft or loss of material	immediate	30 days	10 CFR 20.2201(a)(1)(i); 10 CFR 70.50; 10 CFR 70.52
Whole body dose greater than 0.25 Sv (25 rems)	immediate	30 days	10 CFR 20.2202(a)(1)(i); 10 CFR 70.50
Extremity dose greater than 2.5 Sv (250 rems)	immediate	30 days	10 CFR 20.2202(a)(1)(iii); 10 CFR 70.50
Whole body dose greater than 0.05 Sv (5 rems) in 24 hours	24 hours	30 days	10 CFR 20.2202(b)(1)(i); 10 CFR 70.50
Extremity dose greater than 0.5 Sv (50 rems) in 24 hours	24 hours	30 days	10 CFR 20.2202(b)(1)(iii); 10 CFR 70.50
Whole body dose greater than 0.05 Sv (5 rems)	none	30 days	10 CFR 20.2203(a)(2)(i); 10 CFR 70.50
Dose to individual member of public greater than 1 mSv (100 mrems)	none	30 days	10 CFR 20.2203(a)(2)(iv)
Defect in equipment that could create a substantial safety hazard	2 days	30 days	10 CFR 21.21(d)(3)(i); 10 CFR 70.50
Filing petition for bankruptcy under 11 U.S.C.	none	immediately after filing petition	10 CFR 70.32(a)(9)
Expiration of license	none	60 days	10 CFR 70.38(d)
Decision to permanently cease licensed activities at entire site	none	60 days	10 CFR 70.38(d)
Decision to permanently cease licensed activities in any separate building or outdoor area that is unsuitable for release for unrestricted use	none	60 days	10 CFR 70.38(d)
No principal activities conducted for 24 months at the entire site	none	60 days	10 CFR 70.38(d)

Event	Telephone Notification	Written Report	Regulatory Requirements
No principal activities conducted for 24 months in any separate building or outdoor area that is unsuitable for release for unrestricted use	none	60 days	10 CFR 70.38(d)
Event that prevents immediate protective actions necessary to avoid exposure to radioactive materials that could exceed regulatory limits	immediate	30 days	10 CFR 70.50(a)
Equipment is disabled or fails to function as designed when required to prevent radiation exposure in excess of regulatory limits	24 hours	30 days	10 CFR 70.50(b)(2)
Unplanned fire or explosion that affects the integrity of any licensed material or device, container, or equipment with licensed material	24 hours	30 days	10 CFR 70.50(b)(4)

Note: Telephone notifications shall be made to the NRC Operations Center at (301) 816-5100 or (301) 951-0550. Note that telephone calls to the NRC Regional Office or any other NRC official are not considered notifications.

NRC FORM 335
(2-89)
NRCM 1102,
3201, 3202

U.S. NUCLEAR REGULATORY COMMISSION

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(See instructions on the reverse)

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Final Report

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5. AUTHOR(S)

C. F. Frazier, J. Cruz, S.W. Shaffer

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Division of Industrial and Medical Nuclear Safety
US Nuclear Regulatory Commission
Washington, DC 20555-0001

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Same as 8. above.

10. SUPPLEMENTARY NOTES

11. ABSTRACT *(200 words or less)*

As part of its redesign of the materials licensing process, NRC is consolidating and updating numerous guidance documents into a single comprehensive repository, as described in NUREG-1539, "Methodology and Findings of the NRC's Materials Licensing Process Redesign," dated April 1996, and draft NUREG-1541, "Process and Design for Consolidating and Updating Materials Licensing Guidance," dated April 1996. NUREG-1556, Volume 17, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Special Nuclear Material of Less Than Critical Mass Licenses," dated November 2000, is the seventeenth program-specific guidance developed for the new process and is intended for use by applicants, licensees, and NRC staff, and will also be available to Agreement States. This document combines and updates the guidance found in Regulatory Guide 10.3, "Guide for the Preparation of Applications for Special Nuclear Material Licenses of Less Than Critical Mass Quantities." This final report takes a more risk-informed, performance-based approach to licensing quantities of special nuclear material of less than critical mass, and reduces the information (amount and level of detail) needed to support an application to use this material.

12. KEY WORDS/DESCRIPTORS *(List words or phrases that will assist researchers in locating the report.)*

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CONSOLIDATED GUIDANCE ABOUT MATERIALS LICENSES: PROGRAM-SPECIFIC GUIDANCE ABOUT SPECIAL NUCLEAR MATERIAL OF LESS THAN CRITICAL MASS LICENSES

UNITED STATES
NUCLEAR REGULATORY COMMISSION
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